UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIP MORRIS USA INC., f/k/a PHILIP MORRIS INC, *et al.*, Defendants.	)	Civil Action No. 99-CV-02496 (GK) Next scheduled appearance: Trial (ongoing)

WRITTEN DIRECT EXAMINATION OF
WILLIAM E. WECKER, Ph.D.
SUBMITTED PURSUANT TO ORDER # 471A

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TABLE OF CONTENTS

I. INTRODUCTION 1

A. GENERAL BACKGROUND 1

B. OUTLINE OF OPINIONS TO BE EXPRESSED IN THIS CASE 3

II. THE EXTENT OF COMPENSATION 4

A. EXPERIMENTAL SWITCHING STUDIES 5

B. SPONTANEOUS BRAND SWITCHING STUDIES 7

C. CROSS-SECTIONAL STUDIES 12

D. CIGARETTE PER DAY EQUIVALENTS 16

E. NEW, PREVIOUSLY-UNPUBLISHED ANALYSES IN CHAPTER 4 OF NCI MONOGRAPH 13 SUGGESTING THAT SMOKERS OF LOWER TAR CIGARETTES SMOKE MORE CIGARETTES PER DAY 17

F. FIGURE 4-7: DID SMOKERS WHO SWITCHED TO CIGARETTES WITH LOWER FTC YIELDS IN CPS-I INCREASE THE NUMBER OF CIGARETTES THEY SMOKED PER DAY? 18

1. CHANGE IN TAR AND CHANGE IN NICOTINE 18

2. INCLUDE PEOPLE WHO SWITCHED BUT DID NOT CHANGE THE NUMBER OF CIGARETTES THEY SMOKED PER DAY 24

3. A SIMPLER APPROACH 27

4. OTHER INVESTIGATORS 29

G. FIGURE 4-9: DO SMOKERS OF LIGHT CIGARETTES SMOKE MORE CIGARETTES PER DAY IN THE CALIFORNIA TOBACCO SURVEY DATA? 31

H. CIGARETTES PER DAY CONCLUSION 34

III. THE NEW, PREVIOUSLY-UNPUBLISHED ANALYSES IN MONOGRAPH 13 QUESTION THE EPIDEMIOLOGICAL DATA SHOWING LOWER LUNG CANCER RISK AMONG SMOKERS OF LOWER TAR CIGARETTES 35

A. FIGURE 4-5: ARE THE LOWER LUNG CANCER RISKS AMONG SMOKERS OF LOWER TAR CIGARETTES IN CPS-I BIASED BY CONTROLLING FOR CIGARETTES SMOKED PER DAY? 37

B. THE DECLINE IN U.S. LUNG CANCER DEATH RATES 50

IV. LONGITUDINAL ADVERTISING STUDIES: IS "RECEPTIVITY" CONSISTENTLY ASSOCIATED WITH ACTUAL SMOKING? 54

V. COMMIT: DID THE COMMUNITY INTERVENTION TRIAL FOR SMOKING CESSATION INCREASE SMOKING CESSATION? 63

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I. INTRODUCTION

A. GENERAL BACKGROUND

Q. Would you please tell us your full name and where you live?

A. My name is William E. Wecker, and I live in [DELETED]

Q. How are you employed?

A. I am President of William E. Wecker Associates, Inc., an applied mathematics consulting firm that I founded in 1990.

Q. Please describe to the Court your educational history?

A. As set forth in more detail in my curriculum vitae (JD-065966), I received the Bachelors of Science degree in Basic Sciences from the United States Air Force Academy in 1963. After a period of military service I returned in 1970 to the University of Michigan as a full time graduate student. I received the Master of Science degree and the Ph.D. degree in statistics and applied mathematics from the University of Michigan in 1972.

Q. Between your graduation from the United States Air Force Academy in 1963 and your return to full time student status at the University of Michigan in 1970, how were you employed?

A. I was an officer and a pilot in the United States Air Force. I was also Chief of Protocol for the United States Air Force in Berlin, Germany.

Q. What did you do after you received a Ph.D. from the University of Michigan in 1972?

A. I accepted a position as assistant professor, and later associate professor, at the University of Chicago, where I taught statistics and applied mathematics at the graduate level and conducted research in statistics and applied mathematics. Later, in the 1980s, I moved to the University of California, Davis where I continued to teach statistics and applied mathematics. Then, in 1990, I

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left full-time university teaching and started a consulting company, William E. Wecker Associates, Inc., which I continue to run today.

Q. What was your position when you left full time teaching?

A. I was a full professor, with tenure.

Q. Have you published in the field of statistics and mathematics?

A. Yes, as reflected on my curriculum vitae, I have published over 30 articles in statistics and applied mathematics.

Q. Have you served on the editorial boards of any journals?

A. Yes. I have served on the editorial boards of *The Journal of the American Statistical Association* for four years and *The Journal of Business and Economic Statistics* for eighteen years.

Q. Are you a member of any professional organizations or associations?

A. Yes, I am a member of the American Statistical Association, the Institute of Mathematical Statistics, and the Society for Risk Analysis.

Q. Let's talk a little bit about the work you have done since you founded your company. Your work in this case is being done on behalf of some of the defendants?

A. Yes.

Q. Do you have clients other than tobacco companies?

A. Yes. We consult to a wide variety of clients in business and government: airline companies, aircraft manufacturers, automobile manufacturers, computer companies, insurance companies, pharmaceutical companies, retail companies, telecommunications companies and others. We have worked for local governments and national governments, including the United States Government.

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Q. Have you always charged all of your clients for the work you have done?

A. No. Sometimes we have provided services free of charge. But usually, as in this case, I bill my time on an hourly basis.

Q. Have you previously been accepted as an expert in statistics and applied mathematics?

A. Yes, I have.

Q. Have you ever been a court-appointed expert?

A. Yes, I served as a court-appointed expert in litigation involving the State of California versus the Bank of America.

B. OUTLINE OF OPINIONS TO BE EXPRESSED IN THIS CASE

Q. Dr. Wecker, before we begin discussing the substance of your opinions in this case, I want to set forth the topics the defendants asked you to address to use as a guide in organizing your direct examination. What topics were you asked to address?

A. I was asked to review, comment on, or perform statistical analyses relating to five topics:

(1) The statistical data on the extent of compensation, particularly those in Chapter 3 of NCI Monograph 13, "Compensatory Smoking of Low-Yield Cigarettes" (U.S. Exhibit 58,700).

(2) The statistical data on the lung cancer risks of lower tar cigarettes, particularly the new, previously-unpublished analyses in Chapter 4 of NCI Monograph 13, "Smoking Lower Yield Cigarettes and Disease Risks."

(3) The statistical data and certain published longitudinal studies on the association between "receptivity" toward tobacco advertising and promotions and subsequent smoking.

(4) The statistical data on efficacy of a community intervention to promote smoking cessation, the Community Intervention Trial for Smoking Cessation ("COMMIT").

(5) The work of the Government's experts, Drs. Fisher, Gruber, and Wyant, relating to disgorgement, including estimates of smoking-attributable health-care costs, morbidity, and mortality.

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Q. On which of those five topics are you going to offer opinions today?

A. I have been asked to offer opinions on the first four topics today since those are topics on which the Government's witnesses have already testified.

I have not been asked to offer opinions concerning the last topic at this time because it is my understanding that the Government's experts have not yet testified about that topic and may not do so.

II. THE EXTENT OF COMPENSATION

Q. Let's turn to the first topic on which you've been asked to testify, estimates of the extent of compensation. Is there a mathematical or statistical formula for calculating the extent of compensation?

A. Yes. It is set forth in Chapter 3 of NCI Monograph 13 (U.S. Exhibit 58,700 at 44). The formula is:

$$Compensation = 1 - \left[\frac{\log(\text{marker}_2) - \log(\text{marker}_1)}{\log(\text{yield}_2) - \log(\text{yield}_1)} \right]$$

Q. Is that the formula you used in your work in this case involving compensation calculations?

A. Yes.

Q. What types of compensation studies were discussed in Chapter 3?

A. Chapter 3 of NCI Monograph 13 discusses three different types of compensation studies: (1) short-term and long-term experimental switching studies; (2) spontaneous brand switching studies; and (3) cross-sectional studies.

Q. Chapter 3 of Monograph 13 states at page 44: "Using the equation above, where data are available, the degree of compensation will be reported for the various studies discussed in subsequent sections."

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Did Chapter 3, in fact, report the compensation for each of the studies it reviewed where data was available?

A. No, it did not. Estimates of compensation were reported for the experimental switching studies. But no estimates of compensation were reported for either the spontaneous brand switching studies or for the cross-sectional studies.

Q. Did you calculate the compensation for each of the studies where data was available?

A. Yes, I did.

A. EXPERIMENTAL SWITCHING STUDIES

Q. Chapter 3 of Monograph 13 (at 45-49) reports the estimated compensation in each of the short-term and long-term experimental switching studies. Did you confirm those estimates?

A. Yes.

Q. What was the estimated compensation in the long-term experimental switching studies?

A. The median compensation in the long-term experimental switching studies was 79 percent, which is less than complete compensation.

Q. What was the estimated compensation in the short-term experimental switching studies?

A. The median compensation in the short-term experimental switching studies was 59 percent, which is less than complete compensation.

Q. The Court has already heard testimony that compensation may occur via two different potential mechanisms (1) so-called within cigarette compensation in which

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individual cigarettes are smoked more intensively; and (2) smoking more cigarettes per day.

What form or forms of compensation were taken into account in the experimental switching studies?

A. Both forms of compensation were taken into account. Even considering both forms of compensation, the smokers randomly assigned to smoke lower tar cigarettes, in fact, got less tar and nicotine as measured by biological markers.

Q. Do the experimental studies of compensation have any advantages, from a statistical perspective, compared to the spontaneous brand switching studies or cross-sectional studies?

A. Yes. To isolate the effect of a particular difference between two groups, such as a difference in the brand of cigarettes smoked, it is most helpful if the two groups have no other differences. If groups differ in several ways it may be difficult or impossible to separately distinguish the effects of each of the several differences. We say that the effects are "confounded."

In the experimental studies, people are randomly assigned to smoke cigarettes with different FTC tar yields. The effect of a random assignment is to insure that any differences, other than the one difference being studied, are evenly distributed between the two groups. Thus, randomization ensures that there will be no other systematic difference between the two groups except the one difference being studied, in this case a difference in the yield of cigarettes smoked. Because there is only one systematic difference between the two groups, any difference in outcome between the two groups, in this case a difference in biomarkers of nicotine intake, can be unambiguously traced to a difference in the brand of cigarette assigned.

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In contrast, both the spontaneous brand switching studies and the cross-sectional studies are observational studies. They look at people who have decided on their own to smoke lower or higher tar cigarettes. Such groups are termed "self-selected." The self-selected group that decided to smoke a lower tar yield brand or to switch brands can be expected to systematically differ in any number of ways from the self-selected group that decided to smoke a higher tar yield brand or not to switch brands. The nature and amount of these other differences are not known to the statistician and therein lies the difficulty of isolating the effect of any single difference. While statisticians can attempt to control statistically for these other differences, such statistical controlling is a difficult challenge that often cannot be satisfactorily accomplished. This is so because there may be residual differences in the two self-selected groups that affect nicotine intake but which are not measured at all or which are not measured well. In short, statisticians are less sure, with observational data, that the two groups being compared -- here, smokers of lower and higher FTC yield cigarettes -- are otherwise the same and that the observed differences in biomarkers can be traced unambiguously to the assignment of a different FTC yield brand of cigarette.

B. SPONTANEOUS BRAND SWITCHING STUDIES

Q. Please describe for the Court the two spontaneous brand switching studies reported in Chapter 3.

A. The first study is the Lynch and Benowitz spontaneous brand switching study, "Spontaneous Cigarette Brand Switching: Consequences for Nicotine and Carbon Monoxide Exposure," *Am. J. Pub. Health* 78(9):1191-1194 (1987) (JD-063010). The second is the Peach et al. study, "Phlegm Production and Lung Function Among Cigarette Smokers Changing Tar Groups During the 1970's," *J. Epid. and Community Health* 40(2):110-116 (1986) (JD-063007). Both of these studies interview and obtain information on a group of smokers at baseline, such as

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gender, age, the type of cigarette they smoke and, in one of the two studies, a measure of nicotine intake based on biological markers. The smokers are not assigned the type of cigarettes they will smoke in the future, as was the case in the experimental studies, but some of the smokers spontaneously switch the brand of cigarettes they smoke. This is the self-selected switching group. Other smokers do not switch the brand of cigarettes they smoke. This is the self-selected control group.

After a period of time the participants are contacted again. Information is again obtained, such as the type of cigarette they smoke and a measure of nicotine intake based on biological markers.

The Peach study differed from the Lynch and Benowitz study in one important respect. Because the Peach study did not measure nicotine intake based on biological markers at baseline, it is not possible using Peach et al. to compare nicotine intake levels before and after switching, or to compare nicotine intake levels of smokers who switched to a lower yield cigarette to nicotine intake levels of a control group of smokers with known and similar nicotine intake at baseline.

Q. The Court has already heard the testimony of Dr. Benowitz (Trial Tr. at 4755:2-5) that the article he wrote with Dr. Lynch, "Spontaneous Cigarette Brand Switching: Consequences for Nicotine and Carbon Monoxide Exposure," *Am. J. Pub. Health* 78(9): 1191-1194 (1987) (JD-063010), is the only spontaneous brand switching study in the published literature with measurements of nicotine intake based on biological markers both at baseline and at follow-up which allows for a comparison between the smokers who switched brands to the control group that did not switch brands.

Do you agree, Dr. Wecker?

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A. Yes.

Q. Have you examined the Lynch and Benowitz article?

A. Yes.

Q. From a statistical perspective, what is the best way to assess the extent of compensation in this study?

A. The best way to analyze the study is to compare the change in the daily nicotine intake of the smokers who switched to lower tar and nicotine cigarettes to the change in the daily nicotine intake of the control group that, at baseline, had similar daily nicotine intake.

Q. Why do you want to focus on daily intake as opposed to per cigarette nicotine intake?

A. There are two principal reasons.

The accuracy of the "per cigarette" comparison depends on the accuracy of the reported number of cigarettes smoked per day. When smokers are asked how many cigarettes they smoke per day, they tend to round to approximate numbers -- for example, they may say a pack a day (twenty cigarettes) or half a pack (ten cigarettes). Additionally, the participants in the Lynch and Benowitz study were all enrolled in a smoking cessation program at the beginning of the study. To the extent that smoking fewer cigarettes per day after participating in a cessation program may be perceived as socially desirable, there may have been a tendency for the continuing smokers to underreport the number of cigarettes smoked per day at follow up.

Moreover, the "per cigarette" calculation does not attempt to answer the key question of whether smokers who switch to lower tar and nicotine brands have lower total exposure to tar and nicotine and are, therefore, likely to have lower disease risks, particularly for lung cancer. Information on whether the people who switch brands end up getting less tar and nicotine per

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day answers that key question. Calculations of compensation per cigarette do not answer that key question and may not even accurately measure the amount of tar and nicotine ingested per cigarette because of inaccuracies in reporting the number of cigarettes smoked.

Q. Why should one compare the change in daily nicotine intake of the smokers who switched to lower tar and nicotine cigarettes to the change in daily intake of the control group?

A. It goes back to the issue of confounding I raised earlier. The smokers who switched to lower tar and nicotine brands may differ from the smokers of higher tar cigarettes. One way to attempt to take those potential differences into account and to get closer to the ideal of a randomized experiment is to compare the switchers to a control group, which, at the start of the study, was similar in terms of their daily nicotine intake.

Indeed, Dr. Benowitz agrees with me on this point:

> Benowitz, 2/28/2002 Deposition, *Daniels* at 113:13-16:
>
> Q: So you should compare the people who switched to a lower tar cigarette to those who did not change their brand, right?
>
> A: Right.

Q. Did you compare the change in the daily nicotine of the smokers who switched to lower tar nicotine cigarettes during the course of the Lynch and Benowitz study to the change in the daily nicotine intake of the control group?

A. Yes. I compared the control group, who did not change the tar yield of the cigarette they smoked and whose daily nicotine intake remained essentially unchanged, to the groups who switched to a cigarette with a different yield -- i.e., those who switched to higher yield cigarettes, and those who switched to lower yield cigarettes. Based on these comparisons, I conclude that those who switched to higher yield cigarettes increased their daily nicotine intake and those who switched to lower yield cigarettes decreased their nicotine intake as compared to smokers who

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did not change the tar yield of their cigarettes and whose nicotine intake remained essentially unchanged.

Q. Dr. Benowitz testified at this trial (Trial Tr. at 4757:4-8) that the smokers in this study at baseline who smoked the lowest FTC yield cigarettes had the lowest daily nicotine intake:

> Q: And at the beginning of the study, the people smoking the lowest tar and nicotine cigarettes were taking in the smallest amount of nicotine each day as measured by plasma cotinine; correct?
>
> A. Yes.

Based on your independent review of the reported data, do you agree, Dr. Wecker?

A. Yes, I do. The smokers of the lowest FTC yield cigarettes at baseline had the lowest daily intake of nicotine as measured by blood cotinine.

Q. Likewise, Dr. Benowitz testified at this trial (Trial Tr. at 4757:19-23) that the smokers who switched to lower tar and nicotine cigarettes during the course of this study had the lowest daily nicotine intake at follow-up:

> Q: So the people who switched to a lower tar and nicotine cigarette during the course of this study, they are the ones who at follow up, now they have the lowest nicotine intake per day based on plasma cotinine; correct?
>
> A: Yes.

Based on your own review of the reported data, do you agree with Dr. Benowitz's assessment?

A. Yes, the smokers who switched to lower tar and nicotine cigarettes during the course of the study had, at follow-up, the lowest daily nicotine intake based on plasma cotinine measurements.

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Q. Despite your reservations about calculations of compensation on a per cigarette basis, Dr. Benowitz testified at trial in this case (Trial Tr. at 4761:10-4762:8) that, on a per cigarette basis, compensation was only about 28 percent complete if one compares the calculated per cigarette nicotine intake at follow up for the smokers who switched to lower tar cigarettes to the per cigarette nicotine intake of the control group that did not change the brand of cigarettes they smoked.

Do you agree with Dr. Benowitz?

A. Yes.

C. CROSS-SECTIONAL STUDIES

Q. Let's turn now to the final group of studies discussed in Chapter 3 of Monograph 13, the cross-sectional studies.

Although the Court has already heard testimony about this, what is a cross-sectional study?

A. A cross-sectional study is not an experiment and does not study people at different points in time. It is a snapshot look at people at one point in time.

In the context of Chapter 3 of Monograph 13, the cross-sectional studies asked the smokers what brand of cigarettes they usually smoked, obtained information on the FTC tar and nicotine yields of their usual brands, and measured biological markers of their nicotine intake. Some studies also asked about average cigarette per day consumption.

Q. Dr. Benowitz testified at this trial on November 2, 2004 (4743:20-23) that "cross-sectional studies provide the best estimate of chemical exposure to smokers smoking different brands of cigarettes."

Do you agree with that statement?

A. Yes.

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However, cross-sectional studies have limitations. They do not reveal what happens when people switch brands. They are just snapshots in time. They are not randomized experiments and therefore, as I explained before, one can be less certain that observed differences in nicotine intake can be traced unambiguously to differences in the nicotine yields of the cigarettes smoked.

Nonetheless, the cross-sectional studies do provide an important source of information, particularly since there are many of them and the populations they study tend to be larger than the populations studied in either the experiments or the population studied in the one complete spontaneous brand switching study.

Q. As you indicated earlier, Chapter 3 of Monograph 13 at 44 stated that, "[u]sing the [compensation] equation above, where data are available, the degree of compensation will be reported for the various studies discussed in subsequent sections."

Did Chapter 3 of Monograph 13 report estimates of the degree of compensation from any of these cross-sectional studies?

A. No, it did not. It presented correlation coefficients instead.

Q. Is a correlation coefficient the same thing as compensation?

A. No.

Q. Can a compensation result be calculated from a correlation coefficient?

A. No.

Q. Let me show you an excerpt from the February 28, 2002 deposition of Dr. Benowitz in the *Daniels* case (125:6-9): "Statistically, having a correlation doesn't say anything about what the slope is, and the slope is really what you care about for percent compensation."

Do you agree with this statement by Dr. Benowitz?

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A. Yes.

Q. Did you calculate the percent compensation for the cross-sectional studies included in Table 3-1?

A. Yes, I calculated the percent compensation for the cross-sectional studies included in Table 3-1 where it was possible to do so from the data in the published articles.

Q. Did you calculate the percent compensation over the entire range of FTC nicotine yields or did you focus on a narrower range?

A. I focused my analysis on the percent compensation between smokers of today's "light" and full flavored cigarettes. Specifically, I calculated the percent compensation for smokers of cigarettes of (a) "light" cigarettes with FTC nicotine yields in the 0.6 to 0.8 mg range; and (b) full flavored cigarettes with FTC nicotine yields in the 0.9 to 1.3 mg range.

Q. Why did you choose to compute the percent compensation in that range?

A. For a number of reasons.

I performed this analysis in connection with a "lights" class action case, *Turner,* that was pending in Illinois against defendant R.J. Reynolds Tobacco Company. Reynolds' Camel, Salem and Winston "light" cigarettes were at issue in that case. Their FTC nicotine yields are in the 0.6 to 0.8 mg range; the FTC nicotine yields of their full flavored counterparts -- Camel, Salem, and Winston regular cigarettes -- are in the 0.9 to 1.3 mg range.

I decided not to modify my analysis because brands with FTC nicotine yields in these ranges constitute the bulk of the cigarettes sold in the United States. Moreover, Dr. Benowitz testified (Trial Tr. at 4749:3-7) that the degree of compensation is likely to be highest when comparing smokers of cigarettes in these two ranges.

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Q. Have you prepared a demonstrative that shows the extent of compensation you calculated for the cross-sectional studies?

A. Yes. It is JDEM-060514.

Q. Please explain to the Court what your results were.

A. As you can see, the degree of compensation varied from study to study. The highest percent compensation was 97 percent. Here the compensation was nearly complete. The lowest was -37 percent. Here nicotine intake for the smokers of the light cigarettes was even less, in percentage terms, than the percent difference in FTC nicotine yields. The median value of compensation was 47 percent.

Q. Is that 47 percent median estimate of the compensation an estimate of the median compensation per day or per cigarette?

A. This is an analysis of daily nicotine intake. So, it takes into account any tendency of the lower tar smokers to smoke cigarettes more intensively or to smoke a greater number of cigarettes. Both forms of compensation were accounted for.

Q. In either the *Turner* case or this case, has any expert submitted a report claiming that your calculations of the percent compensation in these cross-sectional studies are wrong?

A. No.

Q. In summary, what do the estimates of compensation for the three different kinds of studies -- experimental switching studies; the one complete spontaneous brand switching study; and the cross-sectional studies -- show about the degree to which compensation occurs?

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A. They show that some compensation does occur, but that it is generally not complete. Based on my review of his trial testimony, Dr. Benowitz agrees (Trial Tr. at 4737:25-4738:9 and 4738:15-18).

The smokers of cigarettes with lower FTC nicotine yields get less nicotine per day than smokers of cigarettes with higher FTC nicotine yields.

D. CIGARETTE PER DAY EQUIVALENTS

Q. Dr. Wecker, is it possible to calculate, on average, how many more cigarettes per day smokers of lower tar cigarettes would have to smoke in order for them to intake the same amount of nicotine as higher tar cigarettes?

A. Yes.

Q. Did you do that?

A. Yes.

Q. How did you do that?

A. The 1993 Coultas et al. study (JD-063062) is one of the studies found in Table 3-1. Coultas et al. (1993) calculates that smokers of lower yield cigarettes have lower nicotine intake than smokers of higher yield cigarettes based on a regression analysis. Coultas' regression analysis shows that a 0.1 mg reduction in FTC yield of nicotine is equivalent to smoking 1.8 fewer cigarettes per day in terms of reduced nicotine intake. Thus, smokers of cigarettes with an FTC yield of 0.7 mg nicotine would need to smoke 5.4 more cigarettes per day to intake the same nicotine as smokers of cigarettes with an FTC yield of 1.0 mg nicotine.

$5.4 = 1.8 \times (1.0 - 0.7)/0.1$

I did my own analysis, similar to the Coultas analysis, but using different data. I studied a group of smokers from the 1998 Health Survey of England (HSE). I found that the smokers of lower yield cigarettes had lower nicotine intake than the smokers of higher yield cigarettes. For

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these smokers a 0.1 mg reduction in FTC yield of nicotine was equivalent to smoking 2.5 fewer cigarettes per day in terms of reduced nicotine intake. Thus, smokers of cigarettes with a measured yield of 0.7 mg nicotine would need to smoke 7.5 more cigarettes per day to intake the same nicotine as smokers of cigarettes with an FTC yield of 1.0 mg nicotine.

$7.5 = 2.5 \times (1.0 - 0.7)/0.1$

Q. What do these analyses imply for smokers of light cigarettes with 0.6 to 0.8 mg FTC nicotine compared to smokers of full flavored cigarettes with 0.9 to 1.3 mg FTC nicotine?

A. Smokers of the light cigarettes (0.6 to 0.8 mg FTC nicotine) would need to smoke 5.4 to 7.5 more cigarettes per day to intake the same nicotine as smokers of full flavored cigarettes (0.9 to 1.3 mg FTC nicotine).

Q. Why did you decide to compute cigarette per day equivalents?

A. For two reasons.

First, it translates reductions in nicotine intake expressed as concentrations of blood cotinine into a more readily understood quantity.

Second, Monograph 13 suggests that smokers of lower tar cigarettes smoke more cigarettes per day. The results from the published literature, such as Coultas, that take into account both more intense smoking of individual cigarettes and the number of cigarettes smoked per day do not support that conclusion.

E. NEW, PREVIOUSLY-UNPUBLISHED ANALYSES IN CHAPTER 4 OF NCI MONOGRAPH 13 SUGGESTING THAT SMOKERS OF LOWER TAR CIGARETTES SMOKE MORE CIGARETTES PER DAY

Q. What previously-unpublished analyses does Monograph 13 present on whether smokers of lower tar cigarettes smoke more cigarettes per day that you want to address?

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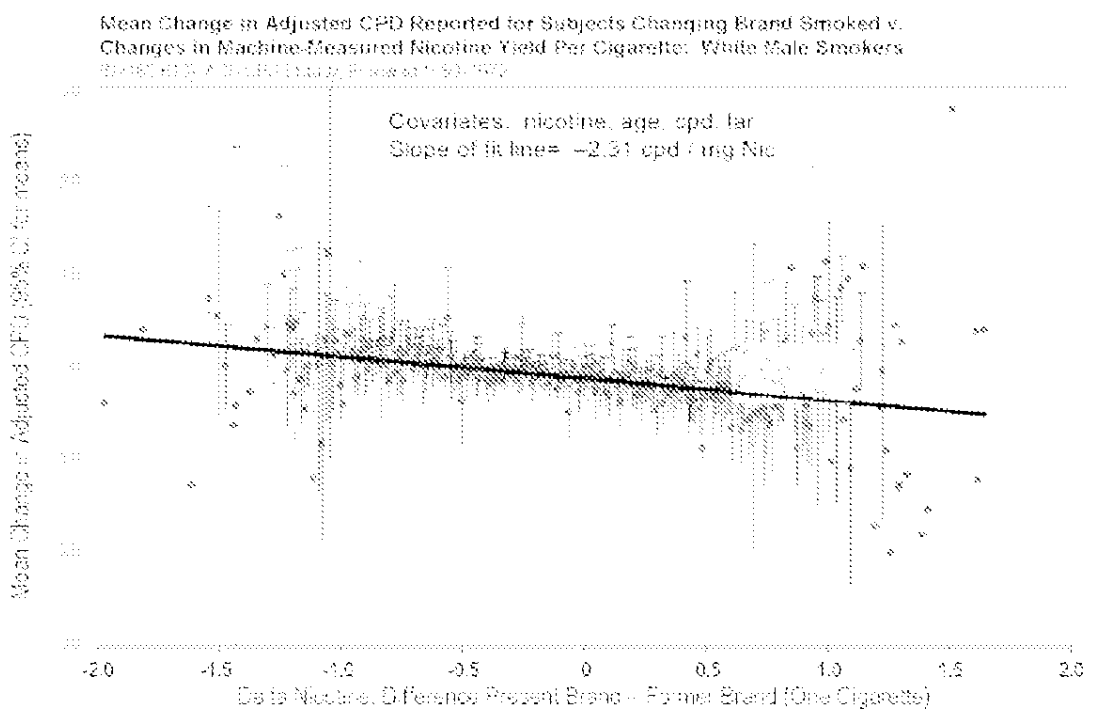
A. There are two: (1) the re-analysis of the longitudinal American Cancer Society CPS-I study that is depicted in Figure 4-7 of Monograph 13; and (2) the analysis of the cigarette per day data from the California Tobacco Survey presented in Chapter 4 and depicted in Figure 4-9.

F. FIGURE 4-7: DID SMOKERS WHO SWITCHED TO CIGARETTES WITH LOWER FTC YIELDS IN CPS-I INCREASE THE NUMBER OF CIGARETTES THEY SMOKED PER DAY?

1. CHANGE IN TAR AND CHANGE IN NICOTINE

Q. Let's start with Figure 4-7. It is depicted here in JDEM-060515:

Monograph 13: Figure 4-7



JDEM-060515

It suggests that CPS-I smokers who switched to lower tar and nicotine cigarettes increased the number of cigarettes they smoked per day.

What did you do to investigate that new analysis?

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A. Through discovery, I obtained the underlying computer programs that Dr. Burns and his co-authors used to generate Figure 4-7. I replicated the analysis and examined the computer programs themselves.

Q. Did you find any errors?

A. Yes, several errors.

Q. What is the first error in the analysis that generates Figure 4-7 that you want to explain to the Court?

A. The first error is conceptual. The analysis that generates Figure 4-7 included both a variable for change in nicotine yield and a variable for change in tar yield, but only the variable for the change in nicotine was considered in Figure 4-7.

Q. Let me interrupt you. Dr. Burns testified at trial (Trial Tr. at 13514:3-5) that the computer program that generates Figure 4-7 does not include variables for both change in tar and change in nicotine. Is that testimony correct?

A. It is not correct. I have the computer program that replicates Figure 4-7. It includes both a variable for change in nicotine and a variable for change in tar.

Q. Sorry for the interruption. Why is it a conceptual error to include variables for both change in tar and change in nicotine, but to look only at the change in nicotine variable?

A. I can show why in steps.

First, Figure 4-7 looks at the change in mean cigarettes per day with a given change in nicotine, holding tar constant. It presumes that one can change the FTC nicotine yield of one's commercial cigarette without simultaneously changing the FTC tar yield. But that's not generally true. As shown below in JDEM-060518, my analysis of the tar and nicotine yields of

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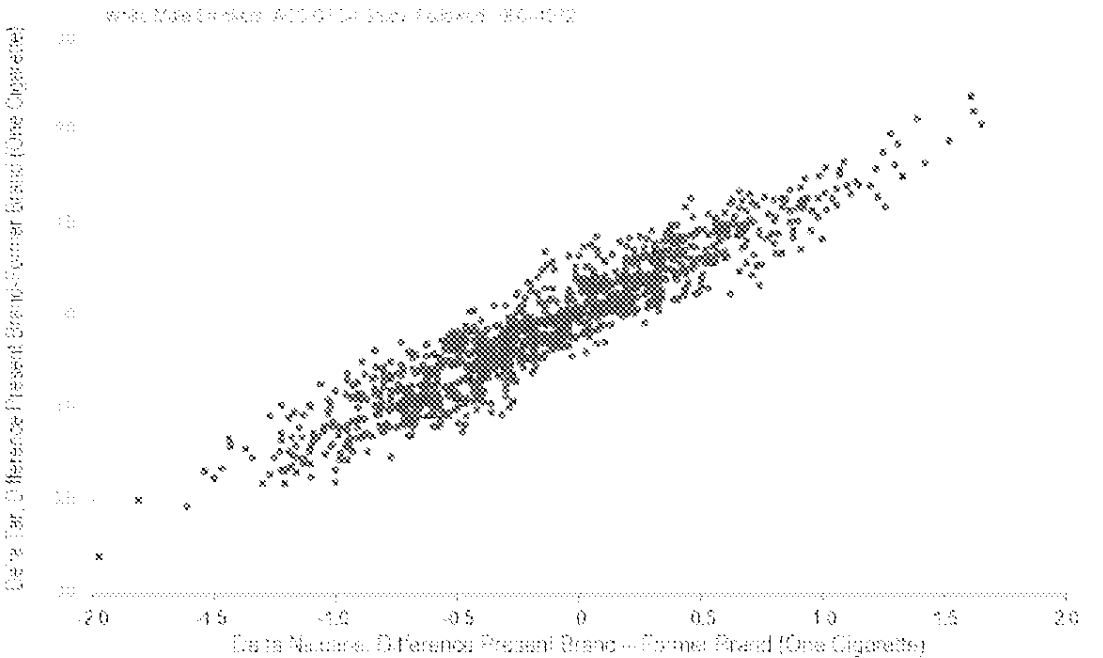
the cigarettes smoked by the individuals included in this analysis shows that the tar and nicotine yields of their commercial cigarettes are highly correlated.

Changes in Nicotine Yield are Highly Correlated with Changes in Tar Yield



JD&M-060518

In short, it is virtually impossible to change the FTC nicotine yield of one's commercial cigarette without simultaneously changing the FTC tar yield in the same direction.

Second, it is a statistical error to include highly correlated predictor variables in an analysis and try to look at only one of them as was done in Figure 4-7.

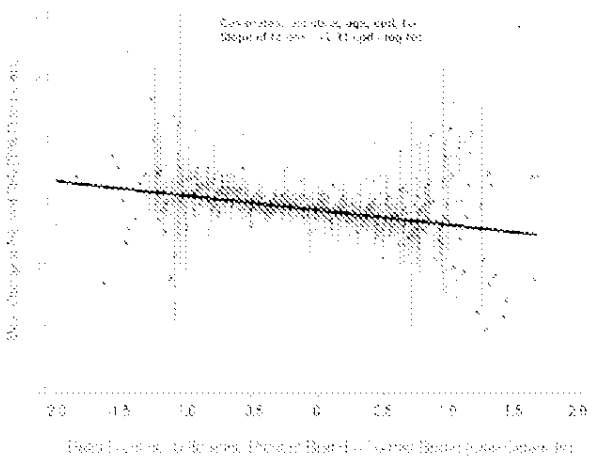
The nature of the error that arises by falsely assuming that one can change the FTC nicotine yield of a cigarette without simultaneously changing the FTC tar yield is easy to illustrate here. Without changing anything in their computer program, I have presented in

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

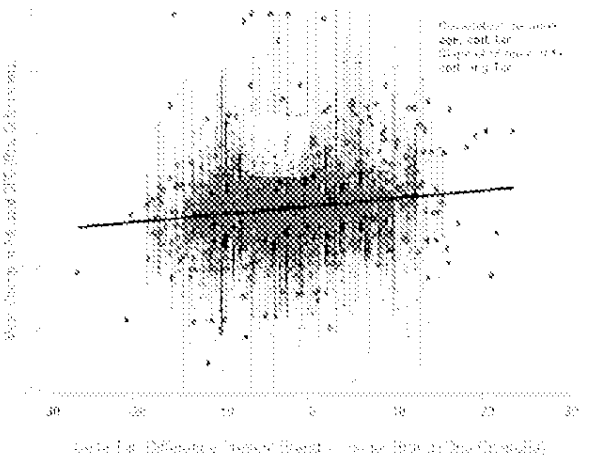
JDEM-060516 the relationship between change in mean cigarettes per day associated with a change in tar alone. I put this new analysis on the same demonstrative as Figure 4-7 (JDEM-060517).

Comparison of Figure 4-7 and JDEM-060516

Figure 4-7



JDEM-060516



As you can see, the analysis based on solely the change in tar variable appears to suggest that smokers who switch to lower tar yield brands decrease the number of cigarettes smoked per day, but when one looks at change in nicotine alone, as in Figure 4-7, the opposite result appears to be true.

But we know this is impossible. As shown above, FTC tar and nicotine yields are highly correlated -- they move together. When smokers simultaneously reduce the FTC tar and nicotine

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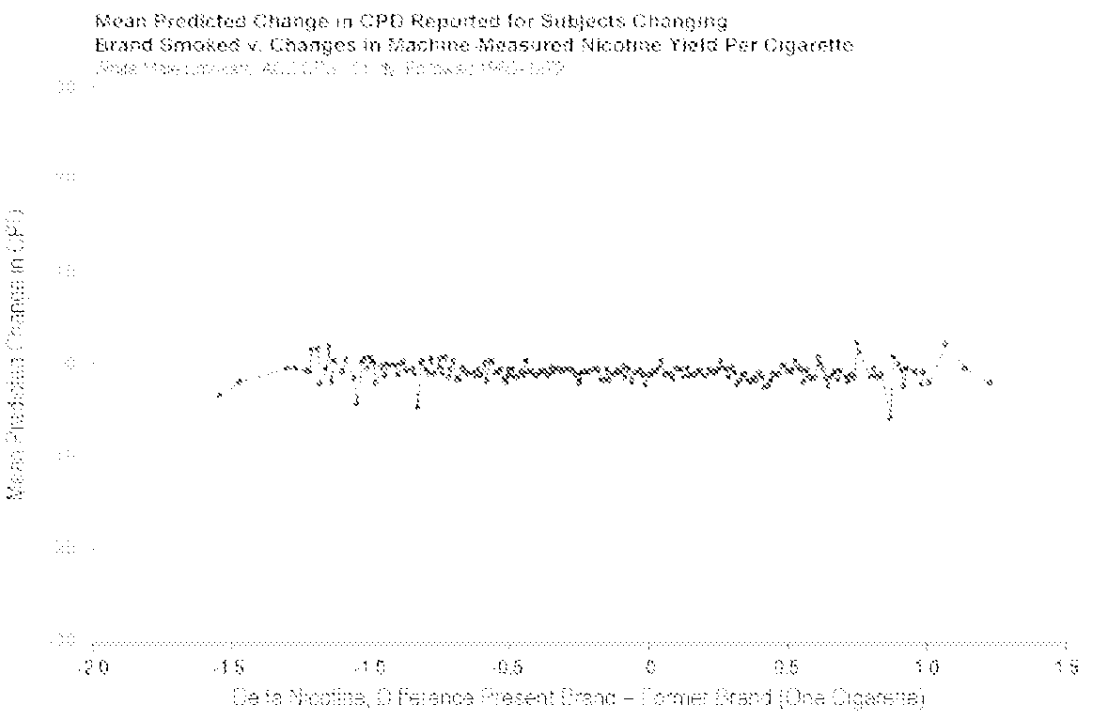
yield of their cigarettes, they simply cannot at the same time increase and decrease the average number of cigarettes they smoke each day.

Q. Were you able to construct an analysis that avoids this conceptual error?

A. Yes. I used the same computer program produced by Dr. Burns that generates Figure 4-7, except, unlike Figure 4-7, I allowed FTC tar and nicotine to change simultaneously.

When I did that, I got the result depicted below in JDEM-060519:

Changes in CPD Among Current Smokers Depicted in Monograph 13, Chapter 4 Figure 4-7



JDEM-060519

Q. What does JDEM-060519 show?

A. It shows no indication of changes in cigarettes per day accompanying a change to a cigarette that is lower in both FTC tar and nicotine.

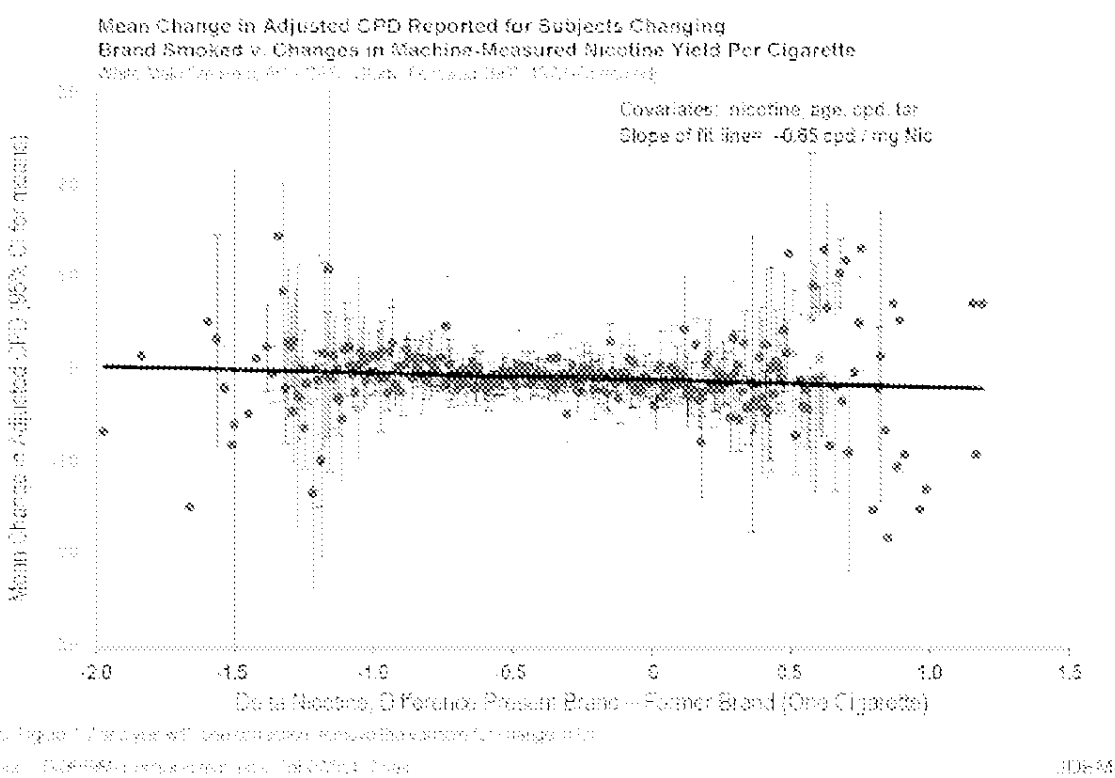
http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Q. Is there another way to do this analysis to eliminate the conceptual error you have identified?

A. Yes. The regression equation underlying Figure 4-7 can be re-estimated after removing the change in tar variable. Because tar and nicotine are highly correlated, the included change in nicotine variable will serve as a proxy for changes in both nicotine and the omitted change in tar variable. That is the only change I made from the analysis presented in Figure 4-7. It still, for example, excludes people who changed the tar and nicotine yields of their cigarettes but did not change the number of cigarettes they smoked per day.

The result is presented in JDEM-060520, below.

Monograph 13, Chapter 4: Figure 4-7 (with 1 Correction)



JDeM-060520

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Q. Please explain what is depicted in JDEM-060520.

A. JDEM-060520 shows a slope of only -0.65 which means that for every 1 mg decrease in nicotine yield, smokers will increase the number of cigarettes they smoke per day by 0.65 cigarettes. In contrast, Figure 4-7 in Monograph 13 suggested that for each 1 mg decrease in FTC nicotine yield, smokers, on average, would smoke 2.31 more cigarettes per day.

Q. When we talked about compensation, you said that the FTC nicotine yields of the Reynolds' lights brands are in the 0.6 to 0.8 mg range while the FTC nicotine yields of their full flavored counterparts are in the 0.9 to 1.3 mg range, a difference of about 0.4 mg FTC nicotine.

How many more cigarettes per day would the regression equation reflected in JDEM-060520 predict that smokers would smoke if they reduced the FTC nicotine yield by 0.4 mg?

A. If I apply the estimated slope of -0.65 to the difference between the Reynolds' light and full flavored brands, it would suggest that smokers who switched and who changed the number of cigarettes they smoked, would, on average, increase the number of cigarettes they smoked per day by 0.26, or about a quarter of a cigarette per day.

2. INCLUDE PEOPLE WHO SWITCHED BUT DID NOT CHANGE THE NUMBER OF CIGARETTES THEY SMOKED PER DAY

Q. What does Chapter 4 of Monograph 13 say Figure 4-7 shows?

A. Chapter 4 of Monograph 13, at page 115, states that "[w]hen the analysis was limited to those who had changed the brand of cigarettes that they reported smoking in sequential follow-up surveys, the slope of mean number of cigarettes per day in relation to change in machine-measured level of nicotine for the brand was -2.31 cigarettes/day/mg nicotine (see Figure 4-7)."

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

This initially led me to believe that the analysis estimated the change in mean number of cigarettes per day for everybody who switched brands.

Q. Was that, in fact, what the analysis did?

A. No.

Q. What does the analysis presented in Figure 4-7 do instead?

A. It estimates not the mean change in cigarettes per day among everybody who switched brands, but only among those individuals who switched brands and changed the mean number of cigarettes they smoked per day.

The analysis ignores those respondents who switched brands but did not change the mean number of cigarettes they smoked per day. Over half of the respondents who changed the tar and nicotine yield of their brands did not change the mean number of cigarettes they smoked per day.

Q. Is that an error?

A. It depends upon the question you want to answer.

No, it is not an error if you want to know how much the change in cigarettes per day was among those respondents who both switched brands and changed the number of cigarettes they smoked.

Yes, it is an error if you want to know for people who changed the tar and nicotine yields of their cigarettes how much did they change the number of cigarettes they smoked per day.

Dr. Burns testified, after he had seen my analysis, that he intended to answer the first question. In this case, he again testified (Trial Tr. at 13515:19-13516:4) that "[Figure 4-7] answers the question of the magnitude of the change proportional to the change in nicotine for those individuals who change [not only their nicotine but also the number of cigarettes they smoked]."

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

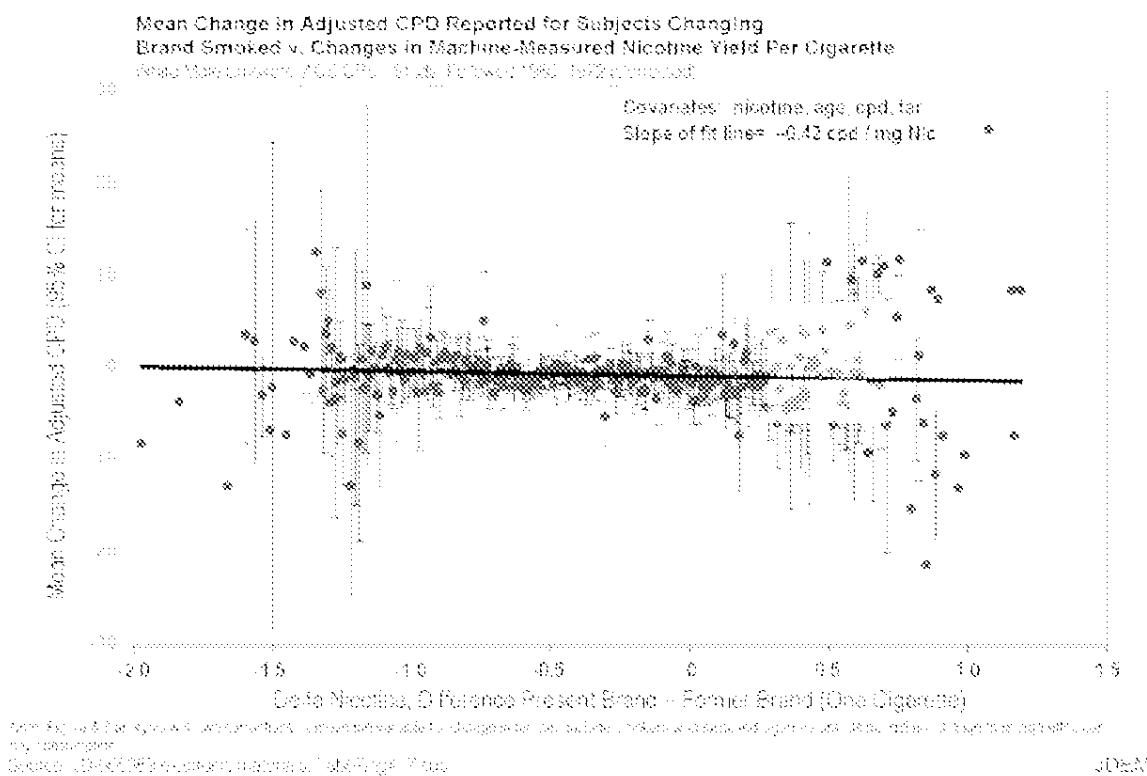
However, the latter question is both the question that the text of Monograph 13 quoted above suggests was being answered and is the more germane question for assessing whether, on average, smokers who switch to lower tar and nicotine brands compensate by increasing the number of cigarettes they smoke.

Q. You mentioned that you had done an analysis. To what analysis do you refer?

A. I built on the analysis presented earlier in JDEM-060520. That analysis corrected the first conceptual error. Now, in addition, I included those individuals who, when they changed the FTC tar and nicotine yields of their cigarettes, did not change the number of cigarettes they smoked each day.

My results are reflected in JDEM-060521.

Monograph 13, Chapter 4: Figure 4-7 (with 2 Corrections)



http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

JDEM-060521 shows a slope of -0.42. In other words, for every 1 mg decrease in nicotine yield, smokers, on average, increased the number of cigarettes per day by 0.42.

If, as before, I apply that estimated slope to the difference in nicotine yield for the Reynolds' light and full flavored brands, it suggests that smokers who switched from a Reynolds full flavored cigarette to a Reynolds light cigarette would increase the number of cigarettes they smoked each day by less than 17/100ths of a cigarette.

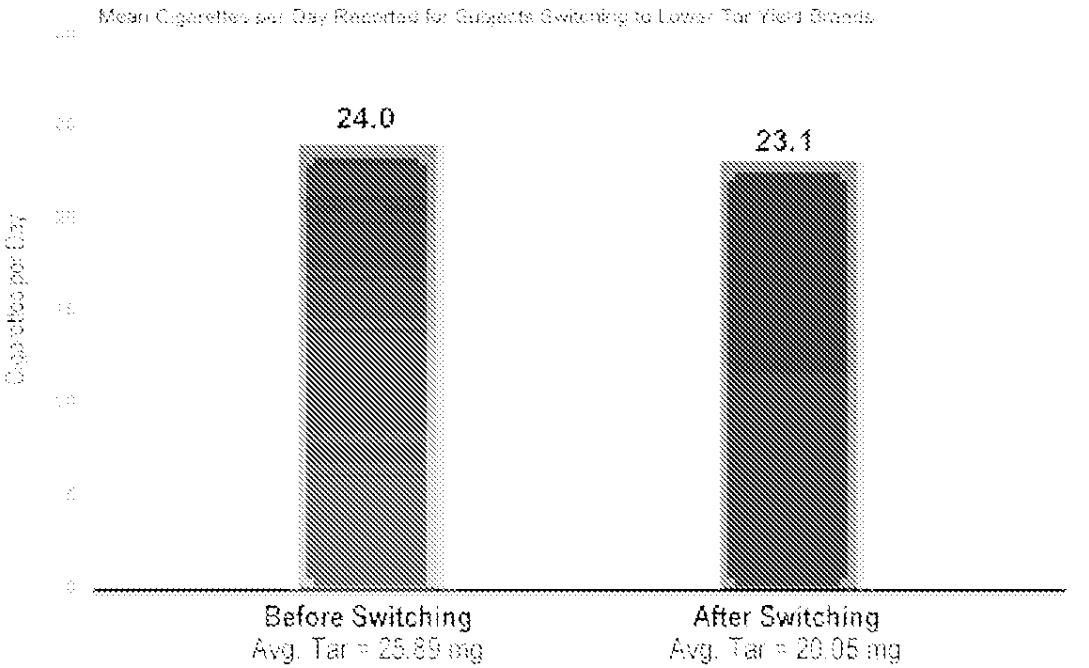
3. A SIMPLER APPROACH

Q. Is there another, simpler statistical approach to answer the question of whether smokers who switch to lower yield brands increase the number of cigarettes they smoke per day?

A. Yes. One way to demonstrate that switching to lower yield brands is not accompanied by an offsetting increase in cigarettes per day is to compare the simple average number of cigarettes per day for current smokers in Chapter 4, Figure 4-7 before and after switching to a lower tar yield brand:

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Average Cigarettes per Day Among Current Smokers in Monograph 13, Chapter 4 Figure 4-7 who Decreased their Machine-Measured Tar Yield per Cigarette



Source: [illegible] JDEM-060523

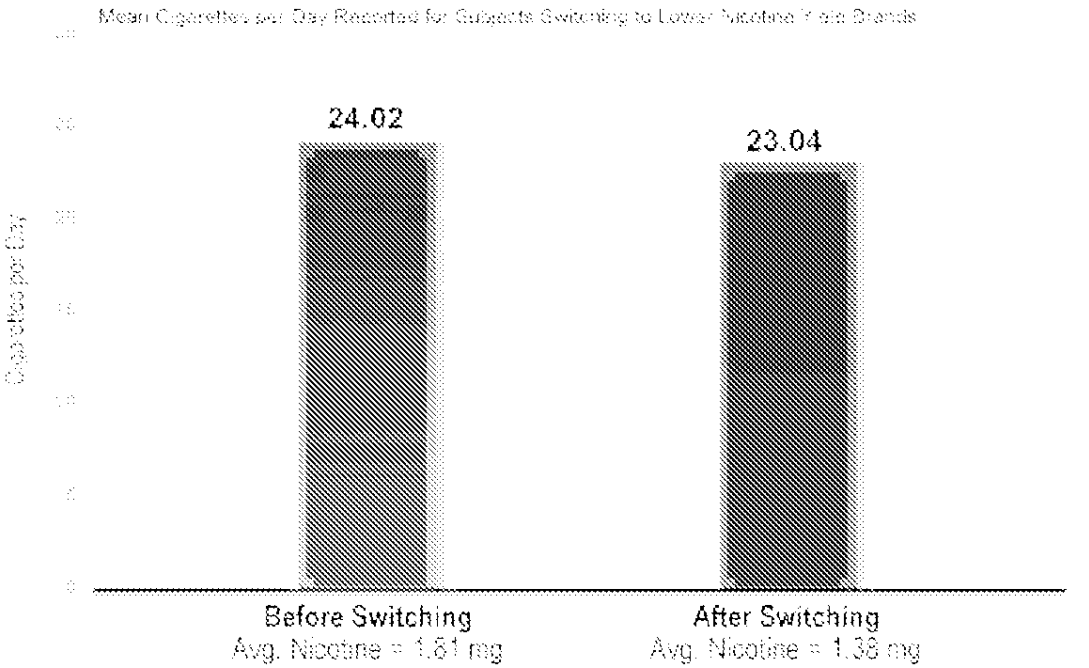
JDEM-060523 shows no increase in cigarettes per day for smokers switching to lower tar yield cigarettes. To the contrary, smokers who switch to lower tar yield cigarettes, on average, decreased their consumption by about one cigarette per day.

Q. Were you able to do a similar analysis for change in nicotine yield?

A. Yes. JDEM-060524 shows a similar result for smokers who switched to cigarettes with lower nicotine yield:

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Average Cigarettes per Day Among Current Smokers in Monograph 13, Chapter 4 Figure 4-7 who Decreased their Machine-Measured Nicotine Yield per Cigarette



JDEM-060524

JDEM-060524 shows no increase in cigarettes per day for smokers changing to lower nicotine yield cigarettes. To the contrary, smokers who switch to lower nicotine yield cigarettes, on average, decrease their consumption by about one cigarette per day.

4. OTHER INVESTIGATORS

Q. Have others examined the CPS-I data to see if smokers who switched compensate by increasing the number of cigarettes they smoke per day?

A. Yes, Garfinkel (1979), Garfinkel (1980) and Garfinkel (1980) each found little or no difference in the number of cigarettes smoked per day for those who increased or decreased the tar and nicotine yield of the cigarettes smoked. Those analyses were conducted using all of the

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white male current smokers who increased or decreased the tar and nicotine yield of the cigarette they smoked.

Garfinkel (1980) (JD-000659) found, at 24, "over a long period of time people tend to smoke the same number of cigarettes a day regardless of the tar and nicotine level."

Q. In response to a question by the Court regarding the analyses employed by Garfinkel and the authors of Chapter 4, Dr. Burns testified (Trial Tr. at 13519:18-21), that "the Garfinkel data looked at groups and looked at the mean values for groups. When you do that you have a very limited ability to see small changes in the number of cigarettes smoked per day." Is Dr. Burns correct?

A. No. The Garfinkel data was more precise than the approach used by the authors of Chapter 4. At page 20 of JD-000659, Garfinkel states quite plainly that "[w]e decided to go back and recode our data by exact number of cigarettes that they reported they had smoked." This increased precision is superior to the method employed by the authors of Chapter 4.

Q. Later on in his response to the Court's question, Dr. Burns testified (Trial Tr. at 13520:13-16), that "[Garfinkel] was also asking a slightly different question, which is what is the mean change in the entire population of individuals as opposed to what is the magnitude of the change in those individuals who do have a change in cigarettes per day." Is Dr. Burns correct on that point?

A. Yes. Dr. Burns is correct that Garfinkel was attempting to answer a different question.

Q. Do you have an opinion regarding which question is more appropriate given the context of the inquiry?

A. Yes.

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The question being explored by Dr. Garfinkel is whether there is empirical evidence that lowering tar and nicotine content of cigarettes may result in increasing the cigarette hazard because smokers will increase the number of cigarettes they smoke. This is a question addressing the effect on the population of the availability of lower tar and nicotine cigarettes.

When exploring a question regarding the effect on a population, it does not make sense to ignore half of the population which engages in the conduct. If one is trying to assess whether smokers who switch to lower tar and nicotine brands, on average, compensate by increasing the number of cigarettes they smoke per day, one ought to look at everybody who switches, not just the people who both switched and changed the number of cigarettes they smoked per day.

Q. Are the conclusions of the Garfinkel (1980) (JD-062670) and Garfinkel (1980) (JD-000659) articles consistent with the conclusions you draw from your analyses?

A. Yes, they are. Both those articles and my analyses support the conclusion that the population of smokers who switch to a lower tar and nicotine yield cigarette do not increase the number of cigarettes they smoke per day.

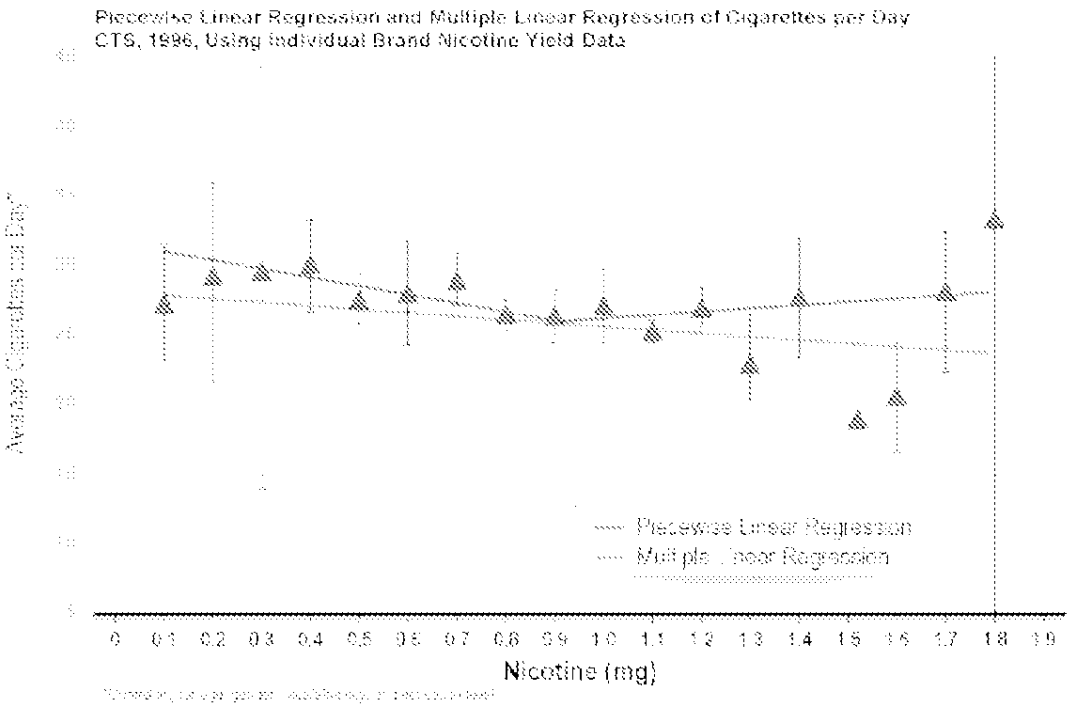
G. FIGURE 4-9: DO SMOKERS OF LIGHT CIGARETTES SMOKE MORE CIGARETTES PER DAY IN THE CALIFORNIA TOBACCO SURVEY DATA?

Q. Let's now talk about the second new, previously-unpublished analysis in Chapter 4 of Monograph 13. What is shown in Figure 4-9?

A. The analysis depicted in Figure 4-9, shown below in JDEM-060528, is a cross-sectional approach to examining the question of whether smokers of lower tar cigarettes smoke more cigarettes per day then smokers of higher tar cigarettes.

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Monograph 13: Figure 4-9



1 JDEAN 060229

2 Specifically, using data from the 1996 California Tobacco Survey (CTS), it looks at daily
3 smokers who were 25-64 years old, smoked five or more cigarettes per day, and had not tried to
4 quit smoking in the previous year. Using the barcode number (Universal Product Code), which
5 the subjects were asked to read from a cigarette pack of a brand that they usually smoke, the
6 authors identified the cigarettes smoked by the subjects and matched the corresponding 1996
7 FTC nicotine yields provided by the FTC.

8 Chapter 4 of Monograph 13 at 117 points to Figure 4-9 as showing that smokers of lower
9 nicotine yield cigarettes smoked more cigarettes per day, stating: "Figure 4-9 shows an increase
10 in number of cigarettes per day for smokers of low-nicotine cigarettes (slope = -2.41 cig/mg
11 nicotine, $P < 0.005$)."

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

1 Q. Did you obtain the data underlying Figure 4-9?

2 A. I did.

3 Q. What did you do to assess the reliability of Figure 4-9?

4 A. One test of the reliability of any analysis is to see if it can be reproduced in a different

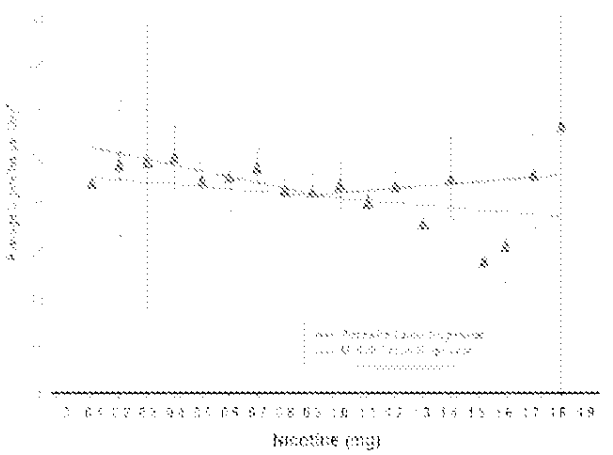
5 data set. I reran the calculation depicted in Figure 4-9 in a comparable data set -- the data from

6 the 1999 California Tobacco Survey. My results are depicted in JDEM-060527. For ease of

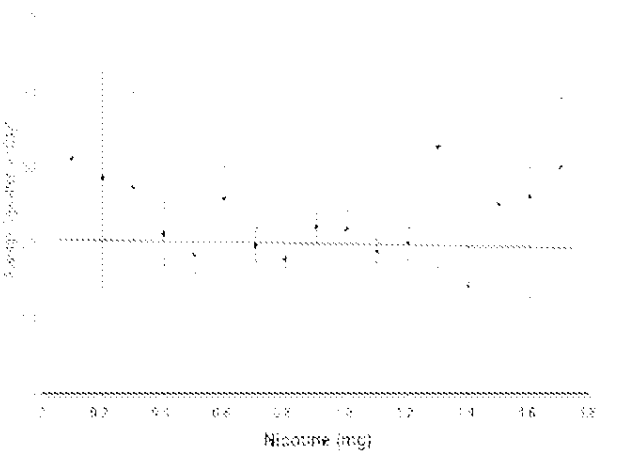
7 comparison, I present the results for the 1999 CTS and 1996 CTS data in JDEM-060529 below:

Comparison of Figure 4-9 and JDEM-060527

Figure 4-9



JDEM-060527



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http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

The same analysis using the 1999 CTS data, instead of the 1996 CTS data, shows no statistically significant relationship between machine-measured nicotine and cigarettes smoked per day.

Q. Why do the results differ?

A. The results depicted in Chapter 4, Figure 4-9 are an artifact of including ultra-low nicotine cigarettes (less than 0.6 mg FTC nicotine) in the analysis.

Q. Have you performed an analysis excluding the ultra-low nicotine cigarettes from the analysis?

A. Yes. JDEM-060530 presents the results of two analyses. The first uses the 1996 CTS data but excludes smokers of ultra-low yield cigarettes. The second is the same, except it uses the 1999 CTS data.

In neither analysis is there a statistically significant relationship between FTC nicotine and cigarettes smoked per day.

H. CIGARETTES PER DAY CONCLUSION

Q. Based on your review and analysis of the evidence presented in Chapter 4 of Monograph 13, have you formed an expert opinion regarding whether the statistical evidence demonstrates that smokers of low nicotine yield cigarettes smoke more cigarettes per day?

A. My opinion is that the statistical evidence supports the conclusion that smokers of lower nicotine yield cigarettes do <u>not</u> smoke more cigarettes per day than smokers of regular nicotine yield cigarettes.

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

III. THE NEW, PREVIOUSLY-UNPUBLISHED ANALYSES IN MONOGRAPH 13 QUESTION THE EPIDEMIOLOGICAL DATA SHOWING LOWER LUNG CANCER RISK AMONG SMOKERS OF LOWER TAR CIGARETTES

Q. Let's switch topics and discuss the second issue you are going to address, the new previously-unpublished analyses in Chapter 4 of Monograph 13 questioning the results of the epidemiological studies showing that smokers of lower tar cigarettes get less lung cancer.

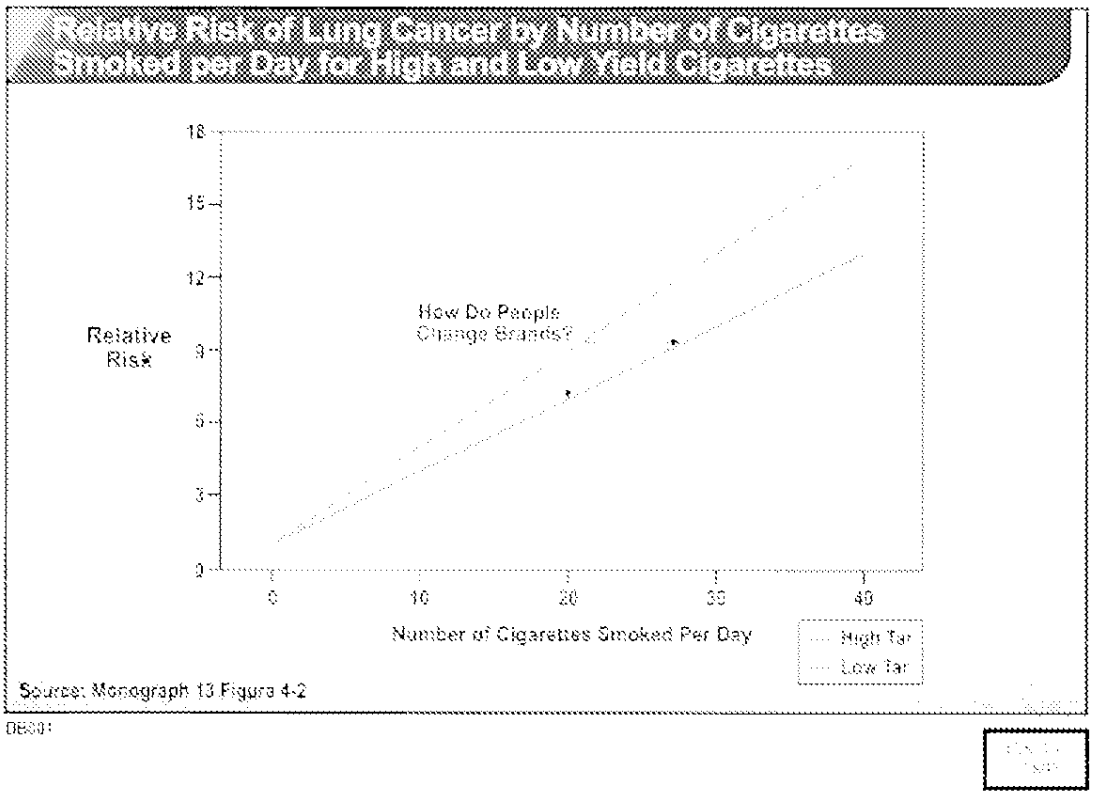
How many new previously-unpublished analyses are there in Monograph 13 on that topic?

A. There are two: (1) the re-analysis of the American Cancer Society CPS-I data presented in Figure 4-5; and (2) an analysis comparing predicted and actual lung cancer rates described on page 140 of Chapter 4.

I would also like to address a hypothetical relationship the authors of Chapter 4 depicted in Figure 4-8.

Q. Let's start with the hypothetical relationship discussed by Dr. Burns in his direct examination, using U.S. Exhibit 17,805:

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf http://www.industrydocuments.ucsf.edu/docs/hfgl0001



Dr. Burns testified (Trial Tr. at 13334:22-13335:9), that:

> We believed, erroneously as it turns out, that when people switched they followed the line that heads straight down at 20. So, a smoker of high-tar cigarettes who smoked 20 cigarettes would drop straight down, would smoke 20 low-tar and nicotine cigarettes. And, therefore, we could compare those two individuals using 20 cigarettes per day as their intensity of smoking.
>
> As it turns out, a substantial fraction of the population doesn't do that. They go along this horizontal line. In order to preserve their ingestion of tar and nicotine when they switch from a high tar cigarette smoking 20 cigarettes a day, they wind up smoking 25 or more cigarettes per day of the low-tar cigarettes.

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: http://www.industrydocuments.ucsf.edu/docs/hfgl0001

Is that statement, that "a substantial fraction" of the population increases the number of cigarettes they smoke per day when switching to a lower tar and nicotine cigarette, accurate?

A. No. First, the quantitative analysis I have performed, together with the published analyses of Garfinkel in the same CPS-I data set, suggest that, on average, smokers do not increase the number of cigarettes per day when they switch.

Second, U.S. Exhibit 17,805 is substantially similar to Figure 4-8 in Monograph 13. Dr. Burns elsewhere has testified that Figure 4-8 is not a quantitative analysis, but, instead, is intended only to illustrate the issue qualitatively. In his *Brown* deposition on December 16, 2002 (186:24-187:4), Dr. Burns testified that:

> [T]he interpretation of Figure 4-8 is that small shifts in cigarettes per day can move people from one line to the other. That's the interpretation of Figure 4.8. It is not a demonstration of the magnitude of risk. It is not intended to be a statement of the magnitude of risk.

Third, I actually have quantified the increase in the number of cigarettes smoked per day that would be necessary to offset the observed lower lung cancer risk among smokers of lower tar cigarettes in CPS-I. In fact, I did so for the analysis of CPS-I lung cancer deaths in CPS-I portrayed in Figure 4-5 of Chapter 4 of Monograph 13. I found that the smokers of lower tar cigarettes would have to increase the number of cigarettes smoked per day by approximately ten to offset the observed lower lung cancer risk per cigarette.

A. FIGURE 4-5: ARE THE LOWER LUNG CANCER RISKS AMONG SMOKERS OF LOWER TAR CIGARETTES IN CPS-I BIASED BY CONTROLLING FOR CIGARETTES SMOKED PER DAY?

Q. The authors of Chapter 4 are critical of the epidemiological studies because they control for cigarettes per day (CPD). At pages 78-79 and 81 of Monograph 13, the authors of Chapter 4 state:

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> If a substantial fraction of lower yield cigarette smokers are compensating by increasing the number of cigarettes smoked per day, then epidemiological studies which use CPD to control for differences in daily dose will overestimate the dose received by lower yield cigarette smokers relative to higher yield cigarette smokers. This overestimation, if present, will bias the risk estimates in favor of finding lower risks among lower yield cigarette smokers when high and low yield cigarette smokers are compared in analyses that use CPD to control for daily dose of smoke received by smokers. Even slight compensation through increasing CPD can substantially bias the risk estimate.
>
> ****
>
> However, control for intensity of smoking across populations using number of cigarettes smoked per day as the measure of dose may result in model misspecification if smokers who switch to low-yield cigarettes compensate by increasing the number of cigarettes that they smoke per day.

What did you do to investigate that?

A. I first examined the analysis that they present in Figure 4-5.

Q. Were you able to obtain the computer programs underlying Figure 4-5?

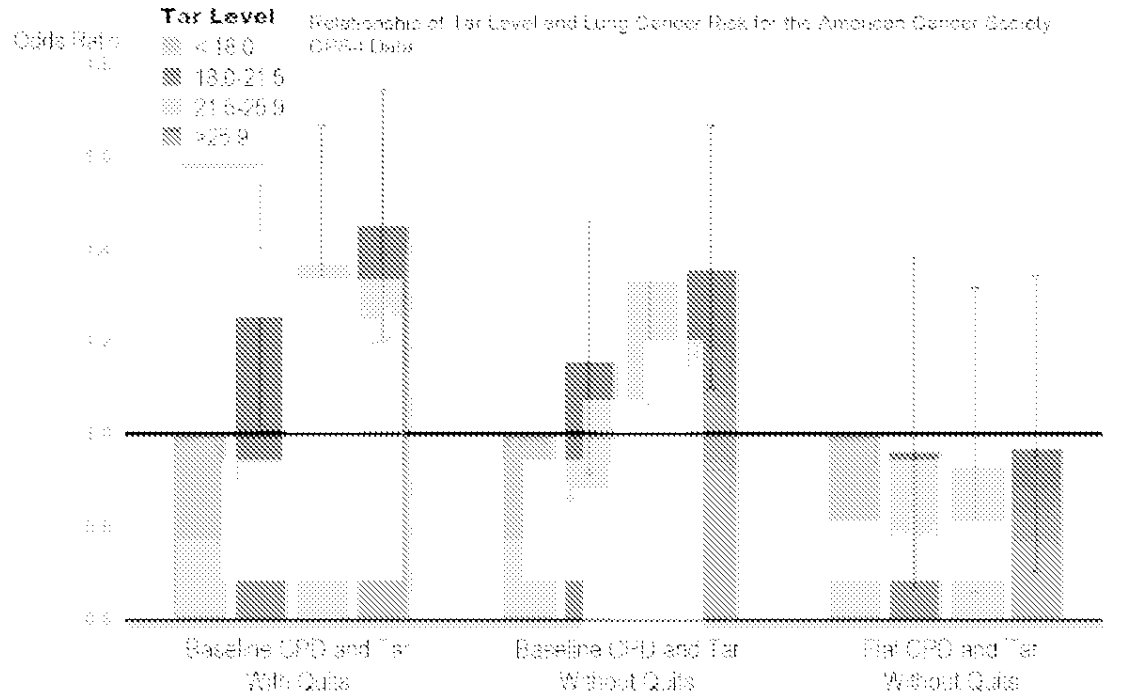
A. Yes, I was.

Q. What is depicted in Figure 4-5?

A. Figure 4-5, reproduced below in JDEM-060531, displays three sets of bars:

http://legacy.library.ucsf.edu/tid/ajq07a00/pdf Source: https://www.industrydocuments.ucsf.edu/docs/hfgl0001

Monograph 13: Figure 4-5 Men (Replication)



JDEAN 060331

Each set of bars is based on a different group of white male smokers from the CPS-I study. No one disputes what the first two sets of bars show or that they were properly estimated. That's not true for the third, rightmost set of bars, however, which the authors suggest shows no reduction in lung cancer risk among "stable" smokers of cigarettes with lower tar yields.

Q. What did the authors of Chapter 4 say about the analysis in the last or third set of bars?

A. It has changed with time.

When I began doing work, I was under the impression that the analysis was intended to be the same as that in the second set of bars except that it was limited to a subset of the

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population that (a) had not changed the number of cigarettes they smoked per day and (b) had not changed the tar yield of the cigarette that they smoked.

I reached that conclusion, in part, based on Dr. Burns' testimony in his deposition in the *Brown* case on December 16, 2002. In two excerpts from pages 139-141 (139:16-140:7; 140:12-141:8), Dr. Burns testified that:

> Q. Now, the final set of bars, it says "flat CPD." What does that mean?
>
> A. That means that the people didn't report a change in cigarettes per day and didn't report a change in tar over the course of the study.
>
> That was – narrowed it down to -- I think a third or less of the population of smokers, but then we had a group who didn't report any change, who were – who were constant across the entire 12-year period as far as we were able to determine from the repetitive questionnaires in the survey.
>
> Q. So that this – the people in the third set of bars were people who, during the course of the follow-ups, did not change cigarettes per day and did not change tar levels?
>
> A. That's correct.
>
> **********
>
> Q. Could you have done the analysis reflected in the third set of bars by using flat CPD but not flat tar? Wouldn't that have increased the number of participants in that analysis?
>
> A. I cannot tell you whether we did that or not. I recall that we did every conceivable iteration of these things, trying to figure out what was going on. I can't tell you whether we did that specific one or not.
>
> Q. Would that be a superior --
>
> A. No. Because the point is you're allowing something to vary, whereas you're holding something else fixed. That doesn't give you an additional insight into what's going on.
>
> The purpose of doing that analysis was to say, you know, if we take and see if we can select out a group of folks who had nothing changed, where they didn't try to quit, they didn't switch cigarettes up and down, they didn't vary from high numbers of cigarettes to low number of cigarettes over the 12-year period, they were sort of stable, if you will, do we see an effect there. And you

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don't see an effect there. Well, does that mean anything? Maybe. Maybe it doesn't.

Additionally, Mr. Shanks, who wrote the computer programs we are discussing, testified in a May 30, 2002 deposition in this case (35:17-36:2) that:

> Q. And the one on the right, again, is a similar analysis, but it's restricted to subjects who both remained current smokers throughout the entire follow-up period and who smoked the same number of cigarettes per day throughout the follow-up period; is that right?
>
> A. Yeah. It says flat CPD and tar.
>
> Q. And tar -- and didn't change their tar category?
>
> A. Uh-huh.
>
> Q. Is that correct?
>
> A. That's right.

So, I was led to believe that the last set of bars was supposed to be the same as the second except it was limited to the smokers who did not change either the number of cigarettes they smoked per day or the tar level of their cigarettes.

Q. Based on the author's own testimony, what did you do?

A. I examined their computer programs that generated the last set of bars in Figure 4-5. I found that it was neither limited to smokers who did not change their cigarettes per day nor limited to smokers who did not change the tar yield of their cigarettes.

I corrected their program so that it was limited to smokers who did not change the cigarettes per day or the tar yield of their cigarettes. When I did that, I found that the third set of bars showed a similar pattern as the first two.

JDEM-060554, a demonstrative I prepared permits you to compare the two versions of Figure 4-5 side by side:

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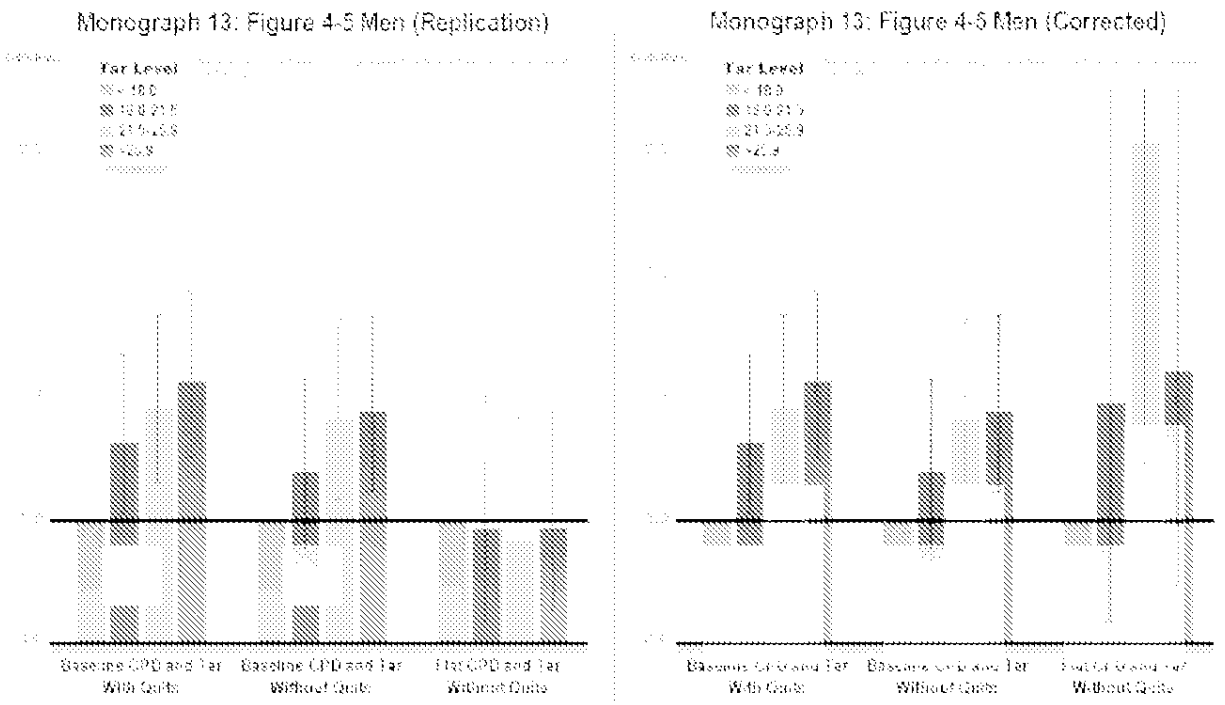
Comparison



JDEM-060534

Q. Is it possible to perform an analysis like that depicted in Figure 4-5 for the women in CPS-I?

A. Yes. I have performed an analysis like the Figure 4-5 analysis for men, but instead, based on data for women smokers. The results are shown in JDEM-060533 and JDEM-060534. JDEM-060533 shows the results that the authors of Chapter 4 would have found if they had done their Figure 4-5 analysis for the women in CPS-I without correcting any of the errors in the Figure 4-5 analysis for men that I discussed above. JDEM-060534 corrects the errors discussed above.

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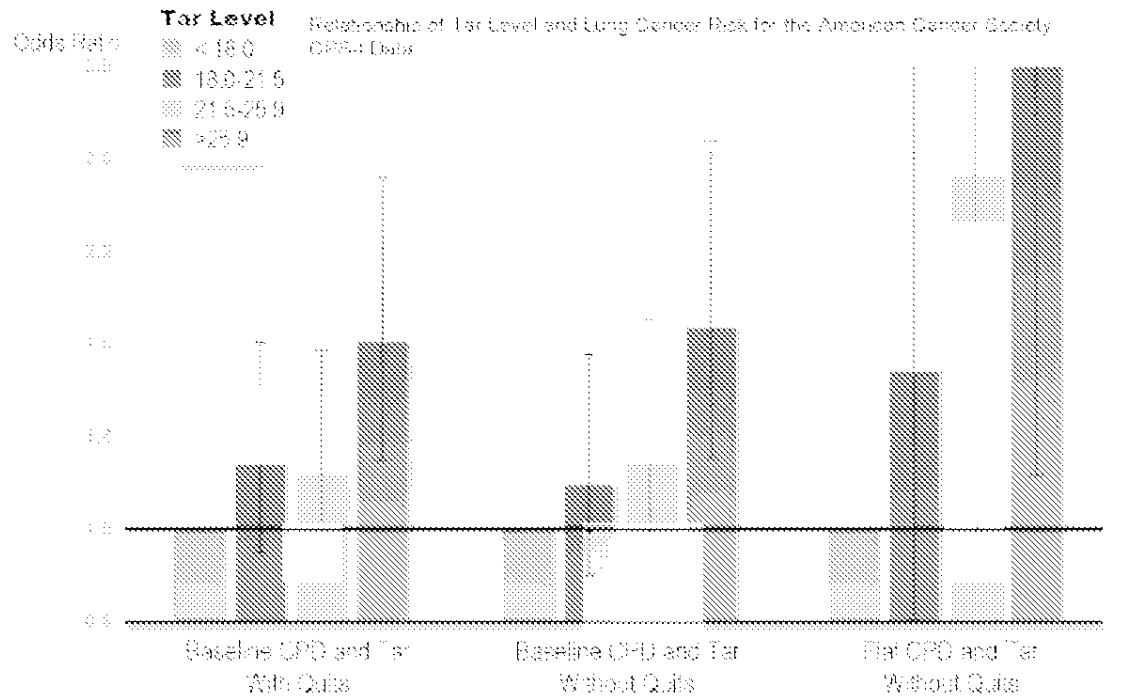
Monograph 13: Figure 4-5 Women (Corrected)



JDEM-060534

Both JDEM-060533 and JDEM-060534 show a significant association between tar level and lung cancer risk in the female population. JDEM-060533 and JDEM-060534 support the conclusion of the previously-published epidemiological studies that lower tar yield cigarettes are associated with lower lung cancer risk.

Q. Is it possible to do an analysis for men and women combined?

A. Yes. JDEM-060535 shows a significant association between tar level and lung cancer risk in the combined (male and female) population:

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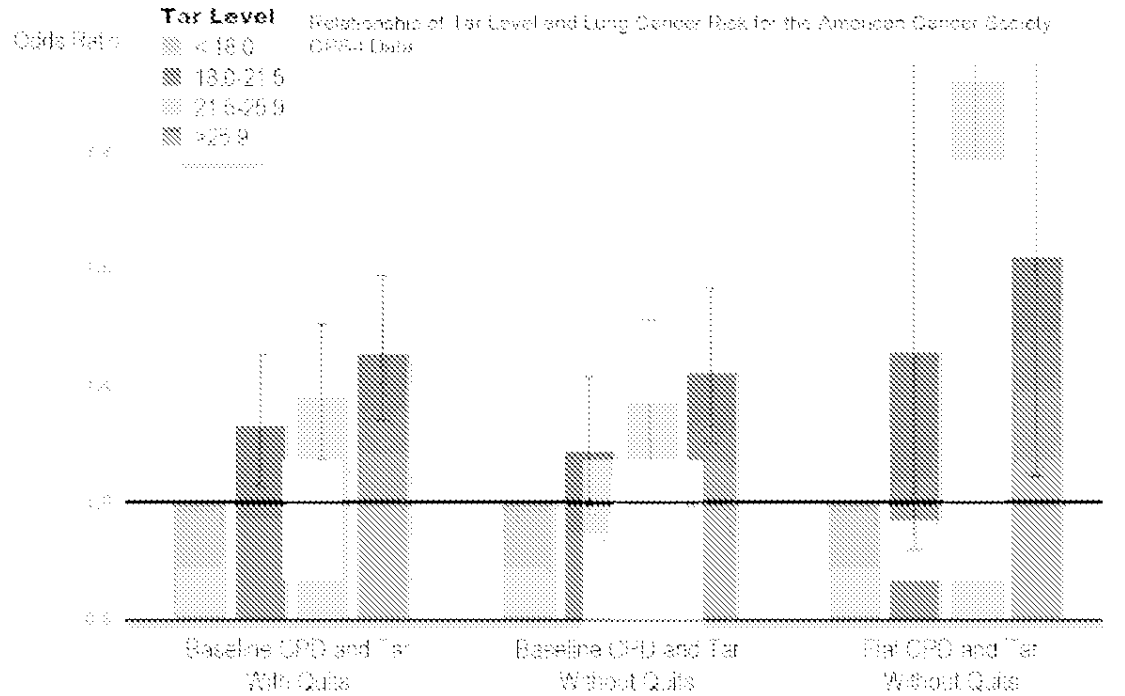
Monograph 13: Figure 4-5 Men and Women (Corrected)



JDEM-060535

Q. What is your interpretation of JDEM-060535?

A. JDEM-060535 supports the conclusion of the previously-published epidemiological studies that lower tar yield cigarettes are associated with lower lung cancer risk.

Q. What conclusion do you draw from your original analysis of Figure 4-5?

A. Consistent with the text of Chapter 4 of Monograph 13, which states at 97-98 that the first and second set of bars are consistent with the dose response relationship between tar yield and lung cancer risk, the corrected third set of bars shown in JDEM-060532 does not contradict the conclusions of the previously-published epidemiological studies that report increasing lung cancer risk with increasing levels of tar among smokers who had a stable smoking history, changing neither the number of cigarettes per day nor the tar yield of their cigarettes.

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Q. Was Dr. Burns confronted with your original analysis of the third set of bars presented in Figure 4-5?

A. Yes, he was. In January 2003 when my report in the *Miles* case was given to him. His statistician, Mr. Shanks, looked at my work.

Q. Has Dr. Burns raised any criticisms of your analysis?

A. Yes, he has raised two criticisms.

Q. What were his criticisms?

A. Dr. Burns noted that the corrected analysis used only "a tiny fraction of the people in the survey" and he has criticized the analysis on the basis that I made a mistake in categorizing the tar values which divide the groups. That critique was in Dr. Burns' February 12, 2003 deposition in the *IPIC* case (647:12-19).

Q. What is your response to the first criticism that the analysis is conducted on a tiny fraction of the people in the survey?

A. It is true that the third set of bars is calculated based on data from 11,712 smokers, which is less than the 74,006 smokers analyzed for the first set of bars and less than the 73,499 smokers analyzed for the second set of bars. It is also true that estimates based on the smaller sample size will exhibit greater variability. But the smaller sample size in the third set of bars, which restricts data to smokers who changed neither the number of cigarettes per day nor the tar yield of their cigarette, is nothing other than a correct implementation of the analysis proposed and described by the authors of Chapter 4.

Q. What about the second criticism, that you used the wrong tar category cut points?

A. My corrections to Dr. Burns's analysis depicted in the third set of bars in JDEM-060532 uses the tar categories <18.0, 18.0 - 21.5, 21.5 - 25.9, and >25.9 that Dr. Burns is recommending.

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These values are shown in the legend of JDEM-060532. In the *Miles* report, I had used the tar categories <17.6, 17.6 - 21.5, 21.5 - 25.8, and >25.8 because those were the values contained in the computer programs produced by the University of California, San Diego that purported to be the computer material underlying the analysis in Figure 4-5. The small difference in tar categories makes no difference at all when it comes to calculating results, such as those that are depicted in JDEM-060532 or Figure 4-5. This is so because there are no smokers in the Figure 4-5 analysis (or the JDEM-060532 analysis) with tar values between 17.6 and 18.0 or between 25.8 and 25.9, so the allocation of smokers to the four tar categories is the same regardless of which tar categories are used.

Q. Did Dr. Burns raise other criticisms?

A. Yes.

Contrary to his testimony prior to seeing my work (Burns, 12/16/02 *Brown* Dep. at 139:16-141:8), Dr. Burns later testified (Burns, 2/12/03 *IPIC* Dep. at 639:20-640:13) that his Figure 4-5 analysis was not intended to be limited to people who did not change the tar yields of the cigarettes they smoked:

> Q. For the analysis depicted by these final four bars, you intended to exclude study subjects who had changed the number of cigarettes per day they smoked or who had changed their tar levels. Is that correct?
>
> A. No, that is not correct. I had misspoke in a prior deposition. I must have been tired.
>
> The point of this analysis is to compare the same tar measurements across the three sets of analyses that select individuals based on either changes in the cigarettes per day or changes in cessation, so it is intended to have the same designation of tar in order to allow comparability across all three groups.
>
> Q. But it's CPD and flat tar. That means flat tar also, doesn't it?

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A. It does not, and probably could have been labeled more clearly.

MR. WOODSIDE: Excuse me. Did you say it doesn't?

THE WITNESS: It does not. I was confused in a prior deposition. I think I was tired.

Q. What did you do after learning of Dr. Burns' changed description of Figure 4-5?

A. I redid the Figure 4-5 analysis to comport with Dr. Burns' revised description of what he intended. Specifically, JDEM-060536 shows the results of my analysis of the same smokers as in the second panel of Figure 4-5 limited to those who did not change their cigarettes per day. There no longer is any requirement that the tar yield of the cigarettes they smoke remain the same.

Q. Did you also do an analysis for men and women together, as you did before?

A. Yes. Those results are shown in JDEM-060537:

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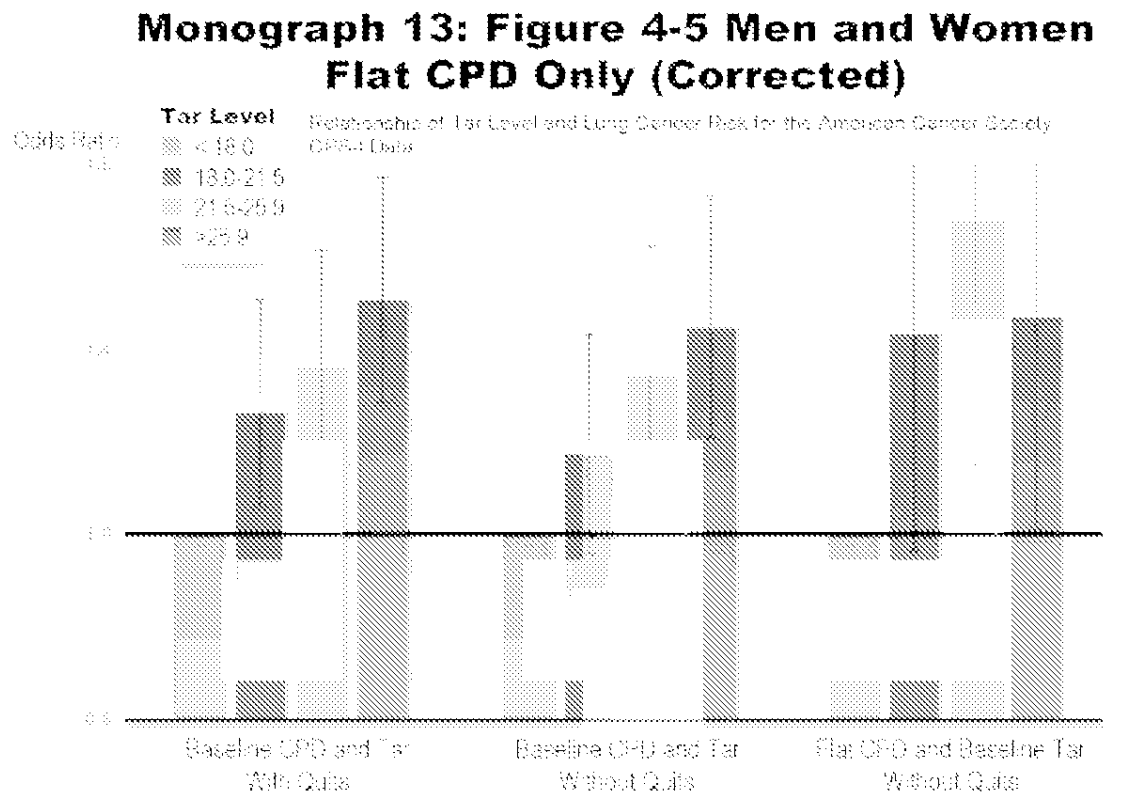

1 JDEM-060537

2 JDEM-060537 supports the conclusion of the previously-published epidemiological
3 studies that lower tar yield cigarettes are associated with lower lung cancer risk.
4 Q. Did you do any other analyses to investigate whether the reported lower lung cancer
5 risk among smokers of lower tar cigarettes in CPS-I was due to a bias introduced by
6 controlling for cigarettes smoked per day?
7 A. Yes. I repeated the analysis in JDEM-060532, which depicts the analysis limiting the
8 population to those who did not change the number of cigarettes per day nor the tar yield of their
9 cigarettes, with one change -- I removed the control for intensity of smoking (CPD). The result
10 is in JDEM-060538:

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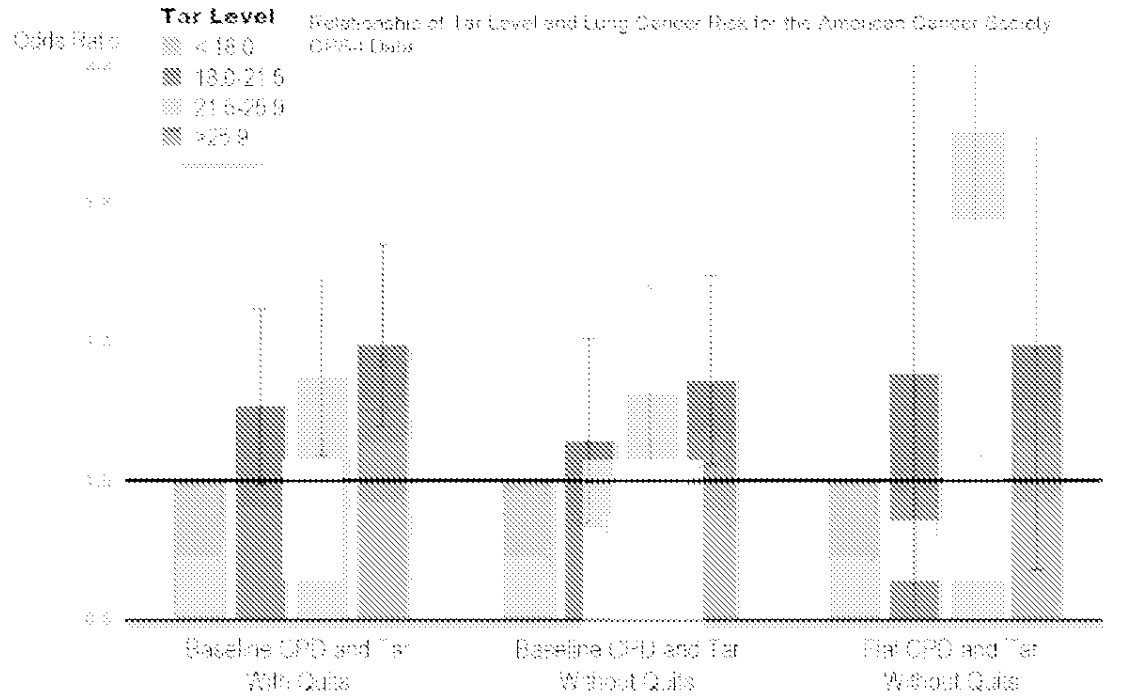
Monograph 13: Figure 4-5 Men Without CPD Variable (Corrected)



JDEM-060538

It shows a significant association between tar level and lung cancer risk. JDEM-060538 supports the conclusion of the previously-published epidemiological studies that lower tar yield cigarettes are associated with lower lung cancer risk.

Q. Is there other empirical support for the proposition that controlling for cigarettes per day does not affect the results of epidemiological studies?

A. Yes. Chapter 4, Table 4-1 includes several studies that report a statistically significant reduction of lung cancer risk at lower tar yields -- without controlling for smoking intensity (CPD). Examples of such studies are Hammond et al. (1977), Hammond et al. (1976), Lee and Garfinkel (1981), Rimington (1981), Benhamou et al. (1985), Lange et al. (1992), and Agudo et al. (1994) (U.S. Exhibit 58,700 at Table 4-1).

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Q. As a statistician, do you have an expert opinion regarding whether the epidemiological studies were biased by controlling for cigarettes per day?

A. Yes, I do have an expert opinion on that topic.

Q. What is your opinion?

A. It is my opinion that there is no empirical evidence in Monograph 13 or the subsequent literature that the epidemiological studies were biased because they controlled for cigarettes per day.

B. THE DECLINE IN U.S. LUNG CANCER DEATH RATES

Q. Let's turn to a question raised by Monograph 13 at page 137: "The question of whether U.S. lung cancer death rates have declined in a way consistent with a lowering of the lung cancer risk of smoking due to the use of lower yield cigarettes can also be examined . . . ."

What is the statistical approach to answering that question described by the authors of Chapter 4?

A. The statistical approach described by the authors of Chapter 4 of Monograph 13 on page 140 is to compare the lung cancer mortality of recent birth cohorts, who smoked mainly lower yield brands, to the mortality that would be predicted for them if they had the same lung cancer mortality as older cohorts who mostly smoked the higher yield brands.

Q. What would such an analysis show if lower tar cigarettes posed a lesser risk?

A. I agree with the authors of Chapter 4, who stated the answer to this question on page 140: "If the most recent birth cohorts have lung cancer death rates that are declining more rapidly than would be predicted from differences in their smoking prevalence (i.e., an effect suggesting a reduction in risk of smoking with lower yield cigarettes), then the difference between actual and

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predicted lung cancer death rates at fixed ages should have a slope when plotted across sequential cohorts."

Q. Did Chapter 4 show a chart or figure that would reveal whether or not "the difference between actual and predicted lung cancer death rates at fixed ages" "have a slope when plotted across sequential cohorts"?

A. It did not.

Q. Did Chapter 4 state in words what such a chart or figure would reveal?

A. Yes. Chapter 4 states on page 140, "When sequential birth cohorts are examined in this manner for age-specific lung cancer death rates at ages under 50, there is no discernible slope for cohorts born after 1930" -- which they interpret as "no evidence to suggest that there is a decline in risk for smokers who would have had higher proportions of their smoking experience using filtered or low-yield cigarettes."

Q. Is that accurate?

A. No.

Q. Please explain.

A. I have prepared a chart in the manner described on page 140 of Chapter 4 that shows "the difference between actual and predicted lung cancer death rates at fixed ages" using data through the year 2000 (JDEM-060548). My chart clearly shows for a cohort of 40 year-olds the "downward slope" arising from "lung cancer death rates that are declining more rapidly than would be predicted from differences in their smoking prevalence (i.e., an effect suggesting a reduction in risk of smoking with lower yield cigarettes)."

Q. Dr. Burns was shown this chart and he testified (Trial Tr. at 13448:1-7), that "because of the scaling, you're not able to compare age specific rates at the younger ages.

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It's a technical limitation. Once you have scaled the data, you need to scale the data in order to match up the model from CPS-I to the actual U.S. mortality data, and that is why the data that was presented was presented as descriptive and was not relied on to draw the conclusions in the volume."

Is Dr. Burns' testimony accurate?

A. No, it is not.

Q. In what respect is it inaccurate?

A. I have used no scaling factor in my chart. Therefore, my chart does not have the limitation Dr. Burns suggests.

Q. Did you make the comparison between predicted and actual lung cancer mortality rates for other specific ages, not just age 40?

A. I prepared a second chart (JDEM-060549) that clearly shows the same "downward slope" for age cohorts from 40 to 50. To highlight that the "difference between actual and predicted lung cancer death rates at fixed ages [has] a slope when plotted across sequential cohorts," I have plotted the slopes using the 1930-34 birth cohort as a common starting point.

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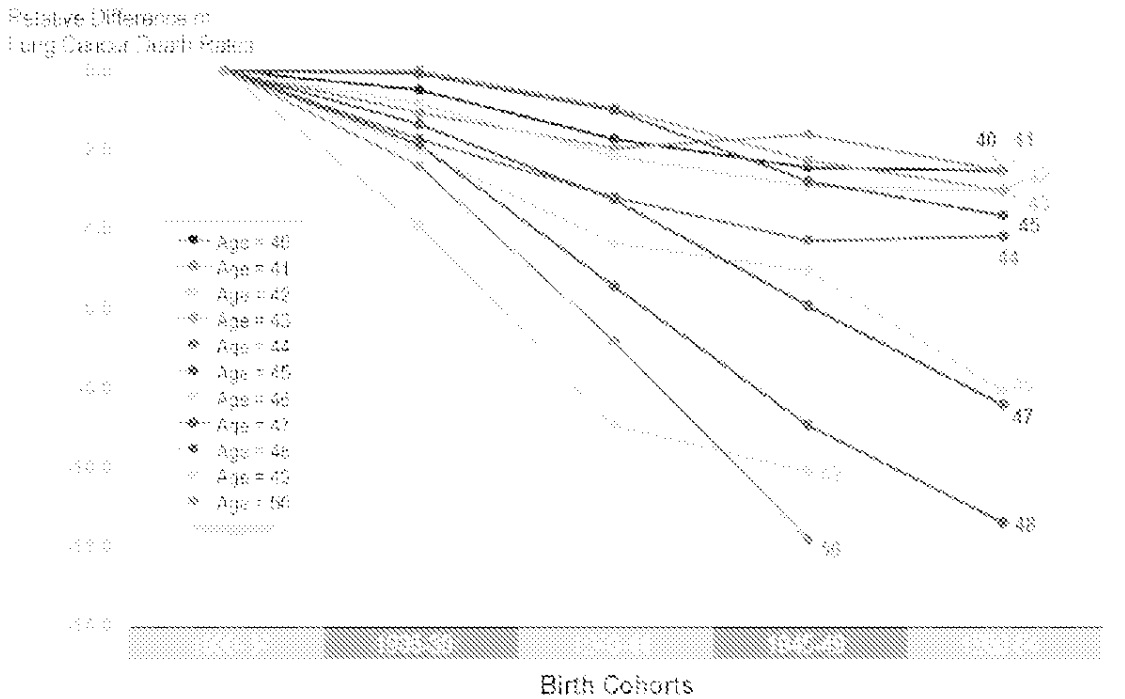
Difference Between Actual and "Predicted" Lung Cancer Death Rates for 40-50 Year-olds Plotted Across Sequential Birth Cohorts



1 JDEM-060549

2 Contrary to the conclusions stated in Chapter 4 at page 140, JDEM-060549 does show a
3 discernible slope when plotted across sequential cohorts for all ages from 40 to 50. According to
4 the authors of Chapter 4, such a slope is indicative of a decreasing risk for the more recent
5 cohorts.

6 Q. What conclusion do you draw from these analyses?

7 A. Chapter 4 states at page 145, that "Lesser risks for more recent cigarettes are one
8 potential explanation for the rapid decline of lung cancer mortality at younger ages in the United
9 Kingdom over recent years." The decline in lung cancer mortality at younger ages in the United
10 States mirrors the decline in lung cancer mortality at younger ages in the United Kingdom. Both
11 of these trends are consistent with lower lung cancer risk for smokers of lower tar cigarettes.

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IV. LONGITUDINAL ADVERTISING STUDIES: IS "RECEPTIVITY" CONSISTENTLY ASSOCIATED WITH ACTUAL SMOKING?

Q. In Dr. Eriksen's testimony (Written Direct at 76:16-78:22; Trial Tr. at 11541:15-11549:2, 11796:9-11825:14, and 11857:22-11866:10), he discussed four U.S. longitudinal studies that examined the association between "receptivity" to defendants' marketing and either subsequent "susceptibility" toward smoking or subsequent actual smoking. The four articles were:

(1) U.S. Exhibit 64,696, Pierce, et al., *Journal of the American Medical Association* 279(7):511-515 (1998);

(2) U.S. Exhibit 72,922, Biener, et al., *American Journal of Public Health* 90:407-411 (2000);

(3) JD-065832, Sargent, et al., *Preventive Medicine* 30:320-327 (2000); and

(4) U.S. Exhibit 74,019, Choi, et al., *American Journal of Preventive Medicine* 22(4):228-233 (2002).

Have you reviewed those four articles, Dr. Wecker?

A. Yes.

During the course of expert discovery in this case, I reviewed and disclosed my work relating to two of the four articles: U.S. Exhibit 64,696, the Pierce article, and U.S. Exhibit 72,922, the Biener article.

I have since reviewed the other two articles: JD-065832, the Sargent article, and U.S. Exhibit 74,019, the Choi article.

Q. Let's talk about U.S. Exhibit 64,696, the Pierce article.

A. Okay.

Q. What population, at baseline, does the Pierce article examine?

A. The baseline population was a group of 12-17 year-old adolescent "nonsusceptible never smokers" in the 1993 California Tobacco Survey.

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Q. How was a "never smoker" defined?

A. A never smoker was defined as an individual who had a negative response to both of the following questions: "Have you ever smoked a cigarette?" and "Have you ever tried or experimented with cigarette smoking, even a few puffs?" (U.S. Exhibit 64,696 at 512.)

Q. What distinguished "nonsusceptible" from "susceptible" never smokers?

A. The "nonsusceptible" never smokers were defined as never smokers who, at baseline, also answered:

(1) "No" to the question "Do you think that you will try a cigarette soon?" and

(2) "Definitely not" to the question "If one of your best friends were to offer you a cigarette, would you smoke it?" and

(3) "Definitely not" to the question "At any time during the next year do you think you will smoke a cigarette?"

(U.S. Exhibit 64,696 at 512.)

Q. What aspect of the nonsusceptible never smoker population did the Pierce study examine?

A. The Pierce study examined whether or not differences in "receptivity" to tobacco advertising and promotions at baseline in 1993 among these nonsusceptible never smokers were associated with smoking or "susceptibility" toward smoking at follow up, about three years later, in 1996.

Q. What did Pierce conclude based on his analysis of these nonsusceptible never smokers?

A. Pierce concluded that "tobacco promotional activities are causally related to the onset of smoking." (U.S. Exhibit 64,696 at 511 (abstract).)

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Q. Please explain the categories of "receptivity" among these "nonsusceptible never smokers" at baseline?

A. They were asked if:

(1) They had ever had a branded tobacco promotional item.

(2) They were willing to use a branded tobacco promotional item.

(3) They could name the cigarette brand of their favorite advertisement.

(4) They could name the cigarette brand they thought was most advertised.

(U.S. Exhibit 64,696 at 512.)

Q. Please explain the survey questions about smoking that baseline nonsusceptible never smokers were asked at the time of the three year follow-up survey?

A. The Pierce article describes the following questions:

(1) "Have you smoked at least 100 cigarettes in your life?"

(2) "Have you ever smoked a cigarette?"

(3) "Have you ever tried or experimented with cigarette smoking, even a few puffs?"

(U.S. Exhibit 64,696 at 512.) Pierce also asked, but did not describe in the article, the number of days on which they smoked in the last 30 days and the average number of cigarettes smoked per day.

Q. What results about "receptivity" and smoking did the Pierce article report?

A. The Pierce article claims that, in the group of nonsusceptible never smokers, "34% of all experimentation in California between 1993 and 1996 can be attributed to tobacco promotional activities." (U.S. Exhibit 64,696 at 511 (abstract).)

Q. What did you do to investigate that claim?

A. I obtained the underlying data that Pierce used. I successfully replicated the Pierce 34 percent calculation. In addition, I calculated the association between "receptivity" and

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smoking, using other measures of current smoking reported at the three year follow-up survey but not analyzed by Pierce. The other measures of smoking include (1) daily smoking (30 of the last 30 days); (2) frequent smoking (20 or more of the last 30 days); and (3) the number of cigarettes smoked per day.

Q. What did you find?

A. Two things.

First, I found that the reported 34 percent increase in "experimentation" associated with higher "receptivity" is not statistically significant.

Second, I found that there was no increase in the other measures of smoking associated with higher "receptivity" among the baseline nonsusceptible never smokers.

Q. Did the Pierce article say whether or not the reported 34 percent increase in "experimentation" associated with higher "receptivity" was statistically significant?

A. He did not. Although the Pierce article reports measures of the statistical significance of other estimates (U.S. Exhibit 64,696 at 514), no claim of statistical significance is made in the article for the reported 34 percent increase in experimentation.

Q. How did you measure the statistical significance of the reported 34 percent increase in "experimentation" associated with higher "receptivity?"

A. I used the same method that Pierce used elsewhere in the article.

Q. What does it mean that the reported 34 percent increase in "experimentation" associated with higher "receptivity" was not statistically significant?

A. It means that the difference between the two sample groups is not sufficient to support a conclusion that any difference at all exists in the rates of "experimentation" between the

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populations from which the samples were selected that can be attributed to differences in "receptivity."

Q. Let's move on to your second finding that you mentioned earlier: that there was no increase in the other measures of current smoking reported at the three year follow-up survey associated with higher "receptivity."

What other measures of smoking did you investigate?

A. I used Pierce's statistical model and data to investigate the association between "receptivity" at baseline and subsequent current smoking, including: daily smoking, frequent smoking, and the number of cigarettes smoked per day.

Q. What did you find?

A. I prepared a table, JDEM-060552, that includes those results as well as the Pierce article's 34 percent estimate for "experimentation."

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Baseline Receptivity and Subsequent Smoking

1996 Smoking Status	Minimal Receptivity Smoking Rate (a)	Higher Receptivity Smoking Rate (b)	Attributable Fraction (c) = (b-a)/b
Experimental Smoker	22.42%	34.10%	34.3%
Daily Smoker	1.50%	1.23%	-22.0%
Frequent Smoker	2.73%	1.66%	-49.0%
Cigarettes per day (CPD)	0.236 CPD	0.231 CPD	-2.2%

Source: [illegible] JDEM-060552

Q. What does JDEM-060552 show?

A. The first row is the result that the Pierce article reported. The next three rows are results that I calculated using the same method Pierce used to calculate the 34 percent figure shown on the first row but substituting other measures of current smoking in place of the "experimental" smoking investigated by Pierce.

None of the three results I calculated shows an increase in current smoking, let alone a statistically significant increase, for the group with greater receptivity to tobacco advertising and promotions. None of the four results shown in the table supports the Pierce assertion that "tobacco promotional activities are causally related to the onset of smoking."

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Q. Since higher "receptivity" is not statistically significantly associated with subsequent increased experimentation, daily smoking, frequent smoking, or smoking more cigarettes per day, do you know what accounts for the second finding in the Pierce article that there is a statistically significant association between "receptivity" and what the article calls "progression in the smoking uptake process" (U.S. Exhibit 64,696 at 511)?

A. Yes. The statistically significant association reported by Pierce arises not because the baseline nonsusceptible never smokers started smoking; it arises instead because some of the baseline nonsusceptible never smokers were classified by Pierce as having become "susceptible" based on their answers to the three year follow-up survey. Pierce combines those who reported some smoking on the follow-up survey with those he determined had become "susceptible" never smokers. He then finds an association of this combined category with some of the four "receptivity" questions:

(1) They had ever had a branded tobacco promotional item.

(2) They were willing to use a branded tobacco promotional item.

(3) They could name the cigarette brand of their favorite advertisement.

(4) They could name the cigarette brand they thought was most advertised.

But actual smoking is not associated with any of the four "receptivity" questions.

Q. Let's talk about U.S. Exhibit 72,922, the Biener article.

What were the main differences between the Biener analysis and the Pierce analysis?

A. There were differences in the baseline groups, levels of receptivity, and levels of smoking.

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Biener and Pierce analyze different baseline groups. Biener analyzed a baseline sample of Massachusetts youths who had not smoked more than one cigarette in their lifetime. Biener also analyzed a baseline sample of Massachusetts youths who were never smokers. Pierce, as we've discussed, analyzed a baseline sample of California youths who were "nonsusceptible" never smokers.

Biener and Pierce distinguish different levels of "receptivity" to tobacco advertising and promotions. Biener distinguished levels of "receptivity" based on responses to two questions:

(1) "Do you have a piece of clothing or other thing that has a tobacco brand name or logo on it?"

(2) "Of all the cigarette advertisements you have seen, which brand's ads do you think attract your attention the most?"

(U.S. Exhibit 72,922 at 408.)

Biener and Pierce distinguish different levels of smoking. Biener distinguishes those who report at the time of the follow-up survey having smoked at least 100 cigarettes, versus those who did not report having smoked at least 100 cigarettes.

Q. Did you analyze the Biener data?

A. No.

Q. Why not?

A. I have not been able to obtain the Biener data.

Q. Did you analyze the Pierce data using the Biener definitions of smoking and "receptivity"?

A. Yes. First, I examined the Pierce baseline nonsusceptible never smokers who reported, at the time of the follow-up survey, having smoked at least 100 cigarettes, which is the Biener

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smoking definition. I found that smoking more than 100 cigarettes was not associated with any of the four Pierce "receptivity" questions.

Second, I examined a baseline sample from the 1993 California Tobacco Survey that had not smoked more than one cigarette in their lifetime, which is the Biener baseline definition. I found for this baseline population that "receptivity," as defined by Biener, was not associated with having smoked, at follow-up, more than 100 cigarettes, which is the Biener smoking definition.

Q. Did Biener report results of her analysis of Massachusetts data where she used only never smokers at baseline?

A. Yes.

Q. What were her results?

A. Biener reported that among Massachusetts baseline never smokers there was no statistically significant association between smoking at least 100 cigarettes, as reported at the time of the follow-up survey, and her two "receptivity" questions.

Q. Let me show you testimony from Dr. Eriksen in this case (Trial Tr. at 11813:3-9):

> Q. And if it was really true that there was this tie that they found between receptivity to marketing and actual establishment of smoking, you would expect to see that same kind of relationship established in other geographical locations, correct?
>
> A. Yes, you'd expect to see it in other studies and other geographical locations.

Q. Do you agree with Dr. Eriksen?

A. Yes.

Q. Why?

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A. The associations claimed in the Pierce and Biener articles, if true, should be consistently reproducible in similar populations using similar methods. I find that there are no consistently reproducible associations "between receptivity to marketing and actual establishment of smoking" (Eriksen Trial Tr. at 11813:3-9). Neither the Pierce article nor the Biener article provide a reliable basis to conclude that "tobacco promotional activities are causally related to the onset of smoking" (U.S. Exhibit 64,696 at 511 (abstract)).

Q. Dr. Wecker, do you know of any longitudinal study that focuses specifically on whether exposure to defendants' promotions, as opposed to "receptivity" to their promotions, is associated with an increase in subsequent smoking by adolescent never smokers?

A. No.

Q. Do you know of any longitudinal study that focuses specifically on whether exposure to defendants' advertising, as opposed to "receptivity" to their advertising, is associated with an increase in subsequent smoking by adolescent never smokers?

A. No. Nor do Pierce and Biener establish a reliable basis to claim a statistically significant relationship between "receptivity" to advertising and subsequent smoking in any group of adolescents.

V. COMMIT: DID THE COMMUNITY INTERVENTION TRIAL FOR SMOKING CESSATION INCREASE SMOKING CESSATION?

Q. Let's turn to another topic.

Dr. Burns testified (Written Direct at 71:21-77:9; Trial Tr. at 13615:21-13643:16) about a comprehensive national smoking cessation program modeled in part upon community intervention trials, such as the Community Intervention Trial (COMMIT) for Smoking Cessation, which Dr. Burns also discussed (Written Direct at 7:10-20).

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Dr. Wecker, have you examined the COMMIT study?

A. Yes. I read the publications concerning the COMMIT study, such as N. Hymowitz, K. Michael Cummings, et al., "Predictors Of Smoking Cessation In A Cohort Of Adult Smokers Followed For Five Years," *Tobacco Control*, 1997:6 (suppl 2):S57-S62 (JD-001162); and The COMMIT Research Group, "Community Intervention Trial for Smoking Cessation (COMMIT): I. Cohort Results from a Four-Year Community Intervention," *American Journal of Public Health*, Feb. 1995, 85(2):183-192 (JD-062352).

In addition, I obtained the underlying data from the COMMIT study, and I replicated the results that appear in the published articles.

Q. Please describe the COMMIT study.

A. The COMMIT study was a 4-year, community-level intervention designed to test whether a comprehensive strategy of emphasizing the health benefits and opportunities for smoking cessation would contribute to an increased quit rate among cigarette smokers.

The COMMIT study separates twenty-two cities into matched pairs. Each pair of cities was then randomly assigned to one of two groups; one group was used as a control and received no anti-smoking interventions, the other group received the anti-smoking campaign information.

Q. What were some of the components of the four-year, anti-smoking intervention?

A. The intervention was comprehensive and aimed at creating demand for smoking cessation services. Among other things, it consisted of mandated:

> Mass media campaigns promoting smoking as a public health problem and promoting cessation.
>
> Sponsored "magnet events" such as "quit and win" contests and the Great American Smokeout.
>
> Comprehensive training in smoking cessation techniques for health-care providers, such as physicians and dentists, to share with their patients.

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Work site annual smoking workshops, promotion of the magnet events, incentives for smoking cessation, and distribution of smoking cessation materials.

Newsletters and information mailed to smokers about smoking cessation resources.

(JD-062352 at 191, Appendix A.)

Q. Did the anti-smoking intervention successfully reach smokers in the eleven intervention cities?

A. Yes. Data were collected and measurements of the success of the intervention in reaching smokers, called "receipt indices," were developed. The summary measure of "receipt" showed statistically significantly greater receipt of the anti-smoking intervention among smokers in the intervention cities. (JD-062352 at 188 and Table 4.)

Q. How was the success of the four-year intervention assessed?

After the interventions were completed, surveys were conducted in each of the twenty-two cities to see if smokers in the cities that received the anti-smoking interventions quit at a higher rate than smokers in the control cities that did not receive the anti-smoking interventions.

Q. What were the results?

A. The control cities without the anti-smoking interventions had an average quit rate of 24.7 percent. The treatment cities with the anti-smoking interventions had an average quit rate of 26.5 percent. The difference of 1.8 percent in quit rates was not statistically significant.

Thus, results from the COMMIT intervention show no statistically significant effect on smoking quit rates.

Q. How did you determine that the difference in quit rate of 1.8 percent was not statistically significant?

A. I did two things.

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First, I replicated the analysis in N. Hymowitz, K. Michael Cummings, et al., "Predictors Of Smoking Cessation In A Cohort Of Adult Smokers Followed For Five Years," *Tobacco Control*, 1997:6 (suppl 2):S57-S62 at S60 (table 2) (JD-001162), where the authors performed an analysis to assess the predictors of smoking cessation. Their analysis shows that the COMMIT anti-smoking treatment cities did not have a statistically significantly higher quit rate when compared to the control cities. In the analysis the authors controlled for some potential confounding factors including: gender, age, race, income, education, alcohol consumption and previous smoking history.

Second, I reviewed The COMMIT Research Group, "Community Intervention Trial for Smoking Cessation (COMMIT): I. Cohort Results from a Four-Year Community Intervention," *American Journal of Public Health*, Feb 1995, 85(2):183-192 (JD-062352), where the authors performed a simplified analysis that appeared to show a statistically significant difference between the two groups of cities. These authors, however, failed to take into account any of the potential confounding factors that were included in the Hymowitz article. I found that the control and the treatment cities had different smoking quit rates prior to the anti-smoking interventions. When these pre-intervention differences were taken into account, I found that there was no statistically significant difference in the post-intervention smoking quit rates between the treatment cities and the control cities.

Q. Thank you, Dr. Wecker.

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